REVIEW

The Danish Prostate Cancer Database

Mary Nguyen-Nielsen[1,2]
Søren Høyer[3]
Søren Friis[4]
Steinbjørn Hansen[5]
Klaus Brasso[6]
Erik Breth Jakobsen[7]
Mette Moe[8]
Heidi Larsson[9]
Mette Søgaard[9]
Anne Nakano[9,10]
Michael Borre[1]

[1]Department of Urology, Aarhus University Hospital, Aarhus, [2]Diet, Genes and Environment, Danish Cancer Society Research Center, Copenhagen, [3]Department of Pathology, Aarhus University Hospital, Aarhus, [4]Danish Cancer Society Research Centre, Danish Cancer Society, Copenhagen, [5]Department of Oncology, Odense University Hospital, Odense, [6]Copenhagen Prostate Cancer Center and Department of Urology, Rigshospitalet, University of Copenhagen, Copenhagen, [7]Department of Urology, Næstved Hospital, Næstved, [8]Department of Oncology, Aalborg University Hospital, Aalborg, [9]Department of Clinical Epidemiology, Aarhus University Hospital, [10]Competence Centre for Health Quality and Informatics (KCKS-Vest), Aarhus, Denmark

Correspondence: Mary Nguyen-Nielsen
Department of Urology, Aarhus University Hospital, Palle Juul-Jensens Boulevard 99, 8200 Aarhus, Denmark
Email maryniel@rm.dk

Aim of database: The Danish Prostate Cancer Database (DAPROCA*data*) is a nationwide clinical cancer database that has prospectively collected data on patients with incident prostate cancer in Denmark since February 2010. The overall aim of the DAPROCA*data* is to improve the quality of prostate cancer care in Denmark by systematically collecting key clinical variables for the purposes of health care monitoring, quality improvement, and research.

Study population: All Danish patients with histologically verified prostate cancer are included in the DAPROCA*data*.

Main variables: The DAPROCA*data* registers clinical data and selected characteristics for patients with prostate cancer at diagnosis. Data are collected from the linkage of nationwide health registries and supplemented with online registration of key clinical variables by treating physicians at urological and oncological departments. Main variables include Gleason scores, cancer staging, prostate-specific antigen values, and therapeutic measures (active surveillance, surgery, radiotherapy, endocrine therapy, and chemotherapy).

Descriptive data: In total, 22,332 patients with prostate cancer were registered in DAPROCA*data* as of April 2015. A key feature of DAPROCA*data* is the routine collection of patient-reported outcome measures (PROM), including data on quality-of-life (pain levels, physical activity, sexual function, depression, urine and fecal incontinence) and lifestyle factors (smoking, alcohol consumption, and body mass index). PROM data are derived from questionnaires distributed at diagnosis and at 1-year and 3-year follow-up. Hitherto, the PROM data have been limited by low completeness (26% among newly diagnosed patients in 2014).

Conclusion: DAPROCA*data* is a comprehensive, yet still young clinical database. Efforts to improve data collection, data validity, and completeness are ongoing and of high priority.

Keywords: prostate cancer, clinical quality indicators, database research

Introduction

The Danish Prostate Cancer Database (DAPROCA*data*) is a nationwide clinical cancer database that prospectively collects data on key clinical parameters for prostate cancer (Table 1). DAPROCA*data* is closely affiliated with the national expert group, the Danish Prostate Cancer Group (DAPROCA), which consists of clinicians and scientists responsible for developing and maintaining national clinical guidelines for the treatment of prostate cancer in Denmark.[1]

Aim of database

The overall aim of DAPROCA*data* and the DAPROCA expert group is to improve the quality of care and management of patients with prostate cancer in Denmark. More

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Table 1 Overview of the DAPROCA*data*

General information		
Patient population	Incident prostate cancer	Data collection since February 2010
Data coverage	Nationwide	22 urological and oncological departments participating in data registration
Data collection	Continuous	Data linkage from central registries combined with online prospective data collection of key clinical variables by treating clinicians
Clinical quality indicators	N=10	
Clinical data registration forms	Diagnosis Clinical Data Registration Form Urology Clinical Data Registration Form Oncology Clinical Data Registration Form	
PROM questionnaires	Data collection since May 2011 At diagnosis 1-year follow-up 3-year follow-up	
Treatment variables	Oncology Surgery Radiation therapy Endocrine treatment	
Pathology variables	Gleason score TNM stage	
Laboratory variable	PSA at diagnosis	
Comorbidity variables[a]	CCI 0= none 1= low 2= medium 3= high	
Administrative variables	Region Hospital site Department	

Note: [a]CCI scores are systematically added to DAPROCA*data* during conversion to the DNKK.
Abbreviations: CCI, Charlson Comorbidity Index; DAPROCA*data*, Danish Prostate Cancer Database; DNKK, Danish National Cancer Clinical Database; PROM, patient-reported outcome measures; PSA, prostate-specific antigen; TNM, tumor, node, and metastasis cancer stage classification.

specifically, the purpose of DAPROCA*data* is to systematically collect key clinical parameters on all patients with incident prostate cancer in Denmark for health care monitoring, quality improvement, and research.

Study population

DAPROCA*data* has collected data on all incident, histologically verified prostate cancer cases in Denmark since February 2010 and as of April 2015, a total of 22,332 patients were registered in the database (Table 2). The inclusion criteria are registration in the Danish Pathology Registry[2] with either: 1) SNOMED codes T77x (prostate and seminal vesicles) and M8xxx3 (all malignant invasive neoplasms in the prostate) or 2) SNOMED codes ÆF4620 (metastases originating from the

Table 2 Summary of patient population (patients diagnosed in the period from 2010 to April 2015) in DAPROCA*data* by treatment group

Treatment groups	Number (N)[a]
Total number of patients with prostate cancer registered in DAPROCA*data*	N=22,332 (2010 to April 2015) N=4,077 (2010) N=4,229 (2011) N=4,279 (2012) N=4,252 (2013) N=4,581 (2014) N=914 (January 2015 to April 2015)
Patients with prostatectomy	N=4,795
Patients with radiotherapy	N=6,118 (total)
Curative intent	N=3,324
Palliative intent	N=2,794
Patients with endocrine therapy	N=7,628
Patients with registered history of chemotherapy	N=508
Patients registered with active surveillance (based on the DAPROCA Urology Clinical Data Registration Form)	N=2,327

Note: [a]Data (as of April 2015) from the DAPROCA*data* 2014 Annual Report.[6]
Abbreviations: DAPROCA*data*, Danish Prostate Cancer Database; DAPROCA, Danish Prostate Cancer Group.

prostate). The exclusion criteria are: 1) inconclusive prostate cancer diagnosis (eg, a relevant M-code registered together with the diagnosis code ÆYYY00, "obs. pro"); 2) patients with temporary personal identification numbers (ie, non-permanent residents); and 3) patients diagnosed in relation to having undergone cystectomy (surgical codes: KKCC10, KKCC11, KKCC20, KKCC21).

Main variables

Clinical data and selected characteristics for patients with prostate cancer at the time of diagnosis are systematically recorded in DAPROCA*data* by a combination of automatized linkage to nationwide health registries (eg, the Danish Pathology Registry, the Danish National Patient Register,[3] and the Civil Registration System[4]) and online registration of key clinical parameters by treating clinicians at the surgical and oncological departments.

Diagnostic and tumor characteristics are retrieved from the Danish Pathology Registry (eg, histological verification, Gleason score, and TNM staging). Supplementary data are obtained from the Danish National Patient Register (eg, medical history and previous surgical procedures prior to prostate cancer). Data on vital status and migration are obtained from the Civil Registration System.[4] Furthermore, an ongoing medical record validation study evaluates the feasibility of including data on cause-specific death from the Danish

Table 3 Clinical quality indicators in DAPROCA*data* (year 2014)

Indicator	Description of indicator	Type of indicator	Standard[a]
Indicator 1: hospital admission after TRUS	Proportion of patients admitted after TRUS-guided biopsy	Process	<5%
Indicator 2a: active surveillance after 1 year	Proportion of patients under "active surveillance" without events after 1 year	Process	>70%
Indicator 2b: active surveillance after 3 years	Proportion of patients under "active surveillance" without events after 3 years	Process	>50%
Indicator 3: positive surgical margin (pT2)	Proportion of RP patients (pT2) with positive surgical margins	Result	<25%
Indicator 4: positive surgical margin (pT3)	Proportion of RP patients (pT3) with positive surgical margins	Result	<40%
Indicator 5: postoperative morbidity	Proportion of patients with postoperative admission >3 days	Result	<5%
Indicator 6: 30-day morbidity	Proportion of patients readmitted with complications <30 days after RP operation	Result	<5%
Indicator 7a: 1-year morbidity	Proportion of RP patients with any hospital admission >30 days and <1 year after operation	Result	Not defined
Indicator 7b: 1-year morbidity	Proportion of RP patients with any hospital admission >30 days and <1 year after radiation therapy	Result	Not defined
Indicator 8: 1-year mortality	Proportion of RP patients deceased <1 year after operation	Result	<1%
Indicator 9a: endocrine treatment for T1/T2	Proportion of patients with T1/T2 disease (<T3; No/Nx; Mo/Mx; PSA<40) receiving endocrine treatment <6 months after diagnosis (M+)	Process	<25%
Indicator 9b: endocrine treatment for N1	Proportion of patients with N1 stage (N1; Mo/Mx/Missing M) receiving endocrine treatment <6 months after diagnosis	Process	>75%
Indicator 9c: endocrine treatment for M1	Proportion of patients with metastases (M1) receiving endocrine treatment <6 months after diagnosis (<T3No; Nx; Mo; Mx; PSA <40)	Process	>75%
Indicator 10a: data completeness	Proportion of diagnosed patients with PSA, cardinal symptoms, and cTNM variables registered in the DAPROCA – Diagnosis Clinical Data Registration Form	Result	>90%
Indicator 10b: data completeness	Proportion of RP patients with registration of treatment history in the DAPROCA – Urology Clinical Data Registration Form	Result	>80%
Indicator 10c: Data completeness	Proportion of patients receiving curative radiotherapy and with a registration of the date of clinical decision making in the DAPROCA – Oncology Clinical Data Registration Form	Result	>90%
Indicator 10d: data completeness	Proportion of patients with completed PROM questionnaires	Result	>80%

Note: [a]Standard =% fulfillment of indicator.
Abbreviations: DAPROCA*data*, Danish Prostate Cancer Database; DAPROCA, Danish Prostate Cancer Group; PROM, patient-reported outcome measures; PSA, prostate-specific antigen; RP, radical prostatectomy; TRUS, transrectal ultrasound; TNM, tumor, node, and metastasis cancer stage classification.

Causes of Death Registry[5] in DAPROCA*data*. Key data related to the index prostate cancer diagnosis are registered by physicians at the treating urological and oncological centers using a specifically developed online registration system. These data include prostate-specific antigen values, prostate cancer-related surgical procedures, and oncological therapy. Separate data registration forms are used for the collection of data at the time of diagnosis and for subsequent urological and oncological information.

A key feature of DAPROCA*data* is the routine collection of patient-reported outcome measures (PROM) since 2011. Patient questionnaires recording adverse effects following treatment and general quality-of-life aspects are collected at diagnosis, and at 1-year and 3-year follow-up.

In 2014, the completeness of PROM questionnaire data from all newly diagnosed patients was only 26%; however, the response proportion at 1-year follow-up among those selected to participate in the initial survey was high (92%).[6] In addition to quality-of-life measurements (eg, pain levels, physical activity, sexual function, depression, urine and fecal incontinence), the PROM questionnaires also collect data on lifestyle factors such as smoking, alcohol consumption, and body mass index.

In 2014, the completeness of online clinical registrations reached 70%.[6] In addition, in 2014, ten clinical quality indicators were defined by the DAPROCA*data* Steering Committee with the aim of improving quality assessment related to the diagnosis, treatment, and recurrence of prostate cancer in

Denmark. The DAPROCA*data* Steering Committee regularly evaluates the clinical relevance and utility of the clinical quality indicators in an ongoing effort toward continued refinement and quality improvement. Table 3 summarizes the clinical quality indicators and standards defined in 2014.

Follow-up

DAPROCA*data* has complete follow-up on all registered patients with prostate cancer. All patients are followed from the date of inclusion in DAPROCA*data* (ie, the date of cancer diagnosis) until death or emigration. This is possible by means of automatized linkage to the Danish Civil Registration System for information on vital status and residency.

Examples of research

Since its establishment in 2010, DAPROCA*data* has created the basis for annual quality improvement reports with detailed analyses of the clinical quality indicators.[6] As the clinical database is young, the data presented in the existing annual reports should be interpreted with caution and especially reports from the very first years after establishment. Data completeness was low during the first year and not all relevant clinical departments participated in online data registration from the start. Nevertheless, the annual reports for the first 5 years document that data validity and completeness have steadily improved, as has the performance of the clinical quality indicators against the predefined set of quality indicator standards (Table 3).

Several validation and epidemiological studies based on data from the initial 5 years of follow-up from 2010 to 2014 are in progress (data not published). DAPROCA*data* will also participate in the DMCG.dk Benchmarking Consortium[7] with planned benchmarking analyses on survival and mortality.

Administration and funding

DAPROCA*data* is under the auspices of the Danish Multi-disciplinary Cancer Groups (DMCG.dk), which is an umbrella organization comprised of 24 national, disease-specific cancer groups and clinical databases.[8] The urological cancer groups and databases are further organized under the Danish Urological Cancer Group.[9] DAPROCA*data* is funded by the Danish Regions[10] and is administered by the Danish Clinical Registries (RKKP).[11] Technical support and data management is provided by the Registry Support Centre for Clinical Quality and Health Informatics (KCKS-Vest).[12] Epidemiological and statistical support in the preparation of annual reports is provided by the Registry Support Centre

for Epidemiology and Biostatistics, North (KCEB-Nord).[13] The nationwide collection of PROM data at all urologic and oncologic centers in Denmark is performed in collaboration with WestChronic.[14,15] In 2015, the Danish Cancer Society collaborated with DAPROCA and WestChronic in a 1-year parallel project on PROM data from prostate cancer patients, but restricted to five participating centers.

The DAPROCA*data* Steering Committee is comprised of clinicians and academic experts representing urology, oncology, pathology, epidemiology, biostatistics, and quality improvement science. In addition to ongoing refinement of the clinical quality indicators and the publication of annual reports, the Steering Committee promotes initiatives to improve data completeness, validity, and coding practices.

Data are collected in accordance with current Danish data protection laws (Sundhedslovens § 196, stk 4 – law nr 546, dated June 24, 2005/law nr 603, dated June 18, 2012). Laws and procedures for data access to DAPROCA*data* are governed by the Data Protection Agency (Datatilsynet) and the National Board of Health (Sundhedsstyrelsen). Applications for access to DAPROCA*data* are reviewed by the Chair and Steering Committee following application to RKKP.

Conclusion

DAPROCA*data* was established in 2010 and is, thus, a relatively young clinical database. Efforts to improve data collection, data validity, and data completeness are ongoing and of high priority. Updated information on DAPROCA*data* is available at DAPROCA's internet homepage: http://ducg.dk/daproca-prostatacancer/.

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Disclosure

References

1. Borre M, Høyer M, Friis S, et al. DaProCa*data* – Dansk Prostatacancer Database (in Danish). *Ugeskrift for Laeger*. 2012;174(42):2556.
2. Bjerregaard B, Larsen OB. The Danish pathology register. *Scand J Public Health*. 2011;39(7 suppl):72–74.
3. Lynge E, Sandegaard JL, Rebolj M. The Danish national patient register. *Scand J Public Health*. 2011;39(7 suppl):30–33.
4. Pedersen CB. The Danish civil registration system. *Scand J Public Health*. 2011;39(7 suppl):22–25.

5. Helweg-Larsen K. The Danish register of causes of death. *Scand J Public Health*. 2011;39(7 suppl):26–29.

6. DAPROCA*data* [webpage on the internet]. Annual Report (in Danish). 2014. Available from: https://www.sundhed.dk/content/cms/86/15686_daproca_årsrapport-2014_kommenteret_20150521final.pdf. Accessed December 23, 2015.

7. DMCG.dk Benchmarking Consortium [homepage on the internet]. Available from: http://dmcg.dk/dmcgdk-benchmarking-consortium/. Accessed December 23, 2015.

8. Danish Multidisciplinary Cancer Groups (DMCG.dk) [homepage on the internet]. Available from: http://dmcg.dk/. Accessed December 23, 2015.

9. Danish Urological Cancer Groups (DUCG) [homepage on the internet]. Available from: http://ducg.dk/. Accessed December 23, 2015.

10. Danish Regions [homepage on the internet]. Available from: http://www.regioner.dk/. Accessed December 23, 2015.

11. Danish Clinical Registries (RKKP) [homepage on the internet]. Available from: http://www.rkkp.dk/. Accessed December 23, 2015.

12. Registry Support Centre for Clinical Quality and Health Informatics (KSKS-Vest) [webpage on the internet]. Available from: http://www.kcks-vest.dk/kliniske-kvalitetsdatabaser/prostata-cancer/. Accessed December 23, 2015.

13. Registry Support Centre for Epidemiology and Biostatistics, North (KCEB-Nord) [webpage on the internet]. Available from: http://www.kea.au.dk/en/ClinicalQuality/CentreClinEpiBiostatNorth.html. Accessed December 23, 2015.

14. Hjollund NHI, Larsen LP, Biering K, Johnsen SP, Riiskjær E, Schougaard LM. Use of patient-reported outcome (PRO) measures at group and patient levels: experiences from the generic integrated PRO system, WestChronic. *Interact J Med Res*. 2014;3(1):e5.

15. WestChronic [Vestkronik-AmbuFlex] [homepage on the internet]. Available from: http://info.ambuflex.dk/. Accessed December 23, 2015.