Quality measurements and patient experiences after radical prostatectomy: A register-based study

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Contents

A: Abbreviations

ACR	American College of Radiology
CAHPS	Consumer Assessment of Healthcare Providers
CMS	Centers for Medicare & Medicaid Services
COSMIN	Consensus-based Standards for the Selection of Health Measurement Instruments
DCE	Dynamic contrast enhancement
DRE	Digital rectal examination
DWI/ADC	Diffusion weighted imaging/apparent diffusion coefficient
EMR	Electronic medical record
EPIC-CP	Expanded Prostate Cancer Index Composite for Clinical Practice
ESUR	European Society of Uroradiology
EUPROMS	Europa Uomo Patient Reported Outcome Study
G8	Geriatric 8
ICHOM	International Consortium for Health Outcome Measurement
bpMRI	Biparametric magnetic resonance imaging
mpMRI	Multiparametric magnetic resonance imaging
MUSIC	Michigan Urological Surgery Improvement Collaborative
NORPEQ	Norwegian Patient Experience Questionnaire
NOTES	Notable Outcomes and Trackable Events after Surgery
PEQ	Patient Experience Questionnaire (PEQ)
PIRADS	Prostate Imaging Reporting and Data System
PSA	Prostate specific antigen
PREMs	Patient-Reported Experience Measures
PROMs	Patient-Reported Outcome Measures

QPP	Quality from the Patients Perspective
RARP	Robotic-assisted radical prostatectomy
SEER	Survival Epidemiology and End Results
T2 WI	T2 weighted images

B: Thesis summary

This thesis concerns the development and use of a local database of patients treated with a robotic-assisted radical prostatectomy (RARP) as a source for quality assurance and research. The database is integrated into patients' electronic medical record (EMR). Administrative and clinical data are automatically imported into the database from structured forms, specifically boxes and drop-down menus in the EMR. The system is efficient and easy to use as registrations do not require re-entry.

In addition to administrative and clinical data, clinical databases should aim to include Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) as both are important for quality assurance. For PROMs, the Expanded Prostate Cancer Index Composite (EPIC) is frequently used in prostate cancer surgery, and the shortest EPIC version is a part of this database. There is, however, no established PREM for RARP patients. We therefore chose to include and test an adapted version of the PREM questionnaire, namely, Quality from the Patients Perspective (QPP), in the database.

When dealing with prostate cancer surgery, it is important to identify men who will most likely benefit from treatment. After the introduction of magnetic resonance imaging (MRI) for diagnostic purposes, information from the MRI is used for making decisions. At Innlandet Hospital Trust, an MRI of the prostate is performed using a biparametric MRI (bpMRI), a protocol without contrast. The MRI data from RARP patients are included in the database. In our most recent publication, we investigated whether information from bpMRI contributed to predicting histological upgrading, i.e., whether the pathological analysis after prostatectomy shows a cancer with a different prognosis than previously assumed in men with low-grade cancer.

All the documents supporting this thesis concern RARP patients enrolled in the local database. The aims, design, study populations, results and conclusions/implications are summarized in Table 1.

Table 1: Summary of the papers

	Aims	**Design**	**Study population**	**Results**	**Conclusions/implications**
Paper 1	To demonstrate and describe the functionality and content of a local quality database	Descriptive	200 RARP patients treated in the period from August 2017 to June 2018	The functionality of the database and adherence from both clinicians and patients were good.	A local quality database integrated in the EMR has value for local quality control, and showed good adherence. Local databases may improve data capture when combined with population-based registries.
Paper 2	To test the construct validity of the questionnaire's Quality from the Patients Perspective (QPP)	Cross-sectional observational study. The QPP questionnaire was filled-in before discharge but after RARP.	265 responders completed an adapted version of the QPP	The answers were skewed distributed, and we were not able to reproduce the theoretical dimensions of the QPP.	The adapted QPP had limited value for RARP patients. Other questionnaires should be considered for measuring the experiences of patients undergoing RARP.

Paper 3	To investigate the associations between patient-reported symptoms and quality ratings of preoperative information about adverse effects and help with adverse effects in patients undergoing RARP	Observational study: a follow-up questionnaire assessing patients' experiences and symptoms 20–42 months after surgery.	235 responders with available baseline data filled-in the follow-up questionnaire	More adverse symptoms present at the follow-up were associated with poorer quality ratings. The majority rated the information as good, irrespective of symptom increase or decrease after RARP.	Experience measures were found to be associated with patient-reported symptoms. Adverse effects could not explain this finding. Although the majority rated the quality of information as good, a share did not, and this highlights the importance of improving communication before an RARP and providing information that is both sufficient and easy-to-understand.
Paper 4	To identify predictors of upgrading from low-grade cancer at RARP in men with bpMRI	Observational study on clinical data collected in the database	130 men with low-grade prostate cancer and pretreatment, bpMRI	PSA density was the only significant predictor of upgrading, but men with suspicious tumors on their MRI had a high probability of upgrading regardless of PSA density.	PSA density is of clinical importance as predictor of upgrading, but only in men with no suspicious tumors on their bpMRI. This finding has clinical importance for men with negative bpMRIs. Due to the low probability of upgrading if PSA density is low, these men should be advised to undergo active surveillance.

C: Summary in Norwegian

Dette prosjektet tar utgangspunkt i en lokal kvalitetsikrinsdatabase for pasienter operert med robot-assistert laparoskopisk prostatektomi (RALP), utviklet for kvalitetssikring og forskning. Databasen er en integrert del av pasientenes elektroniske journal. Administrative og kliniske opplysninger blir automatisk overført til databasen ved bruk av strukturerte skjemaer som er konstruert med rullgardinmenyer og bokser. Systemet er enkelt å bruke og en unngår dobbeltdokumentasjon.

I tillegg til administrative og kliniske data, bør en kvalitetssikringsdatabase inneholde pasientrapporterte utfallsmål (PROMs – patient-reported outcome measures) og pasientrapporterte erfaringer (PREMs – patient-reported experience measures). For pasienter med prostatakreft er Expanded Prostate Cancer Index Composite (EPIC) et validert og etablert spørreskjema for å evaluere utfall. Den korteste versjonen av EPIC, EPIC-CP, er en del av denne databsen. Det eksisterer imidlertid ikke noe etablert eller anbefalt PREM for denne pasientgruppen. Vi valgte derfor å inkludere PREM skjemaet Kvalitet fra Pasientenes Perspektiv i databasen og teste dette for pasienter behandlet med RALP.

Pasienter med prostatakreft er en heterogen gruppe, for noen vil sykdommen utvikle seg langsomt og de dør av andre årsaker, mens andre har en sykdom som utvikler seg raskt. Av den grunn er det viktig å identifisere hvilke menn som med størst sannsynlighet vil profitere på behandling. Etter at MR ble en rutinemessig undersøkelse for disse pasientene, blir funnene på MR også brukt i risikogruppering av pasienter med prostatakreft. Ved Sykehuset Innlandet HF blir MR av prostata utført med en forenklet protokoll (biparametrisk MR – bpMR). I den siste publikasjonen i dette arbeidet ønsket vi å se på om funn på bpMR kunne bidra til å sannsynliggjøre hvilke menn med lavgradig prostatakreft behandlet med RALP som har stor sannsynlighet for at deres prostatakreft blir histologisk oppgradert, det vil si at vevsprøvene etter operasjon viste en sykdom med annen prognose enn antatt på forhånd.

Alle pasientene i prosjektet er operert med RALP og er inkludert i den lokale kvalitetsikringsdatabasen. Formålene, studiedesign, populasjon og konklusjoner er summert opp i tabellen under:

Tabell: Oppsummering av artiklene

	Formål	Design	Studiepopulasjon	Resultater	Konklusjoner
Artikkell 1	Å demonstrere/beskrive funksjonaliteten og innholdet i den lokale kvalitetssikrinsdatabasen.	Deskriptiv.	200 RALP pasienter fra august 2017 til juni 2018.	Funksjonaliteten av databasen var god. Det var høy grad av kompletthet, både på kliniske og pasient-rapporterte data.	En lokal database integrert i elektronisk journal fungerer for kvalitetssikring. Ved å kombinere flere registere, for eksempel regsitere som dette med de nasjonale, kan komplettheten av data øke.
Artikkel 2	Å teste konstruksjonsvaliditeten av spørreskjemaet Kvalitet fra Pasientens Perspektiv (KUPP).	Tverrsnittstudie. KUPP ble fylt ut mens pasientene var inneliggende etter RALP.	265 menn som besvarte en adaptert versjon av KUPP.	Svarene var distribuert med takeffekt og de teoretiske dimensjonene i KUPP kunne ikke reproduseres.	Den adapterete versjonen av KUPP har begrenset verdi for RALP pasienter og andre instrumenter for å måle pasienterfaringer hos denne pasientgrupen bør vurderes.

Artikkel 3	Å undersøke assosiasjonen mellom pasient-rapporterte symptomer og opplevd kvalitet på informasjon om bivirknionger og hjelp med bivirkninger hos pasienter operert med RALP.	Observasjonsstudie. Et oppfølgingskjema som omfattet pasienterfaringer og symptomer ble fylt ut 20-42 etter behandling.	235 menn med baseline data fylte ut oppfølgingsskjemaet.	Økning av symptomer ved oppfølging var assosiert med lavere pasientopplevd kvalitet på informasjon. De fleste oppga at informasjonen var god, uavhengig av om de rapporterte økning av symptomer eller ikke.	Pasienterfaringer ble funnet å være assosiert med pasient-rapporterte symptomer. Bivirkninger kunne ikke forklare funnet. Selv om de fleste rangerte kvaliteten på infomasjon som god, var den en del som ikke gjorde det, og det setter fokus på å gi forståelig og tilstrekkelig informasjon samt på å forbedre kommunikasjon.
Artikkel 4	Å identifisere prediktorer for histologisk oppgradering fra lav-gradig prostatakreft etter RALP hos menn med bpMR.	Observasjonsstudie ved bruk av kliniske data fra databasen.	130 menn operert med RALP som hadde med lav-gradig prostatakreft på biopsi og bpMR før behandling.	PSA density var eneste signifikante prediktor for oppgradering, men menn med suspekt prostatakreft på MR hadde høy sannsynlighet for oppgradering uavhengig av PSA density.	PSA density har klinisk betydning for å forutse oppgradering, men bare hos men med suspekt prostatakreft på bpMR. Menn uten funn på MR og lav PSA density bør vurdere aktiv overvåkning istedenfor radikal behandling.

D: Articles in this thesis

Paper 1

TECLA—An innovative technical approach for prostate cancer registries

Ola Christiansen, Ola Bratt, Erik Skaaheim Haug, Arild Vaktskjold, Anders Selnes, Marit Jordhøy

Scand J Urol 2019: doi: 10.1080/21681805.2019.1634148

Paper 2

Construct validity of the questionnaire quality from the patients' perspective adapted for surgical prostate cancer patients

Ola Christiansen, Jūratė Šaltytė Benth, Øyvind Kirkevold, Ola Bratt, Marit Slaaen

JPatientExp.2021:doi:10.1177/2374373521998844

Paper 3:

Experience measures after radical prostatectomy: A register-based study evaluating the association between patient-reported symptoms and quality of information

Ola Christiansen, Jūratė Šaltytė Benth, Øyvind Kirkevold, Ola Bratt, Marit Slaaen

Healthcare 2022: doi.org/10.3390/healthcare10030519

Paper 4:

Predictors of upgrading from low-grade cancer at prostatectomy in men with biparametric magnetic resonance imaging

Ola Christiansen, Ola Bratt, Øyvind Kirkevold, Jūratė Šaltytė Benth, Papthmakulendran Manoharan, Anders Selnes, Erik Skaaheim Haug, Marit Slaaen

Cent European J Urol. 2021: doi: 10.5173/ceju.2021.0217

E: Background

Reasons for this study

The best way to measure quality in healthcare is a matter of debate. The perception of what quality is and means depends on a person's standpoint. The view on quality may differ among patients, healthcare workers, health authorities and politicians. This makes quality measurement challenging, and there is need for different measurements to evaluate quality of care. The topic of this thesis is quality of care for patients with prostate cancer receiving radical surgery. Observational data from clinical registries are the most important sources for evaluating quality and making comparisons between institutions [1]. However, data from registries may have several pitfalls. In order to provide reliable information, collected data should be as complete as possible. Missing data and low capture rates limit the value of the information obtained from registries. A specific challenge is how to capture patient-reported data, which often is lacking [2]. Additionally, the burden of registration presents a problem for both patients and clinicians.

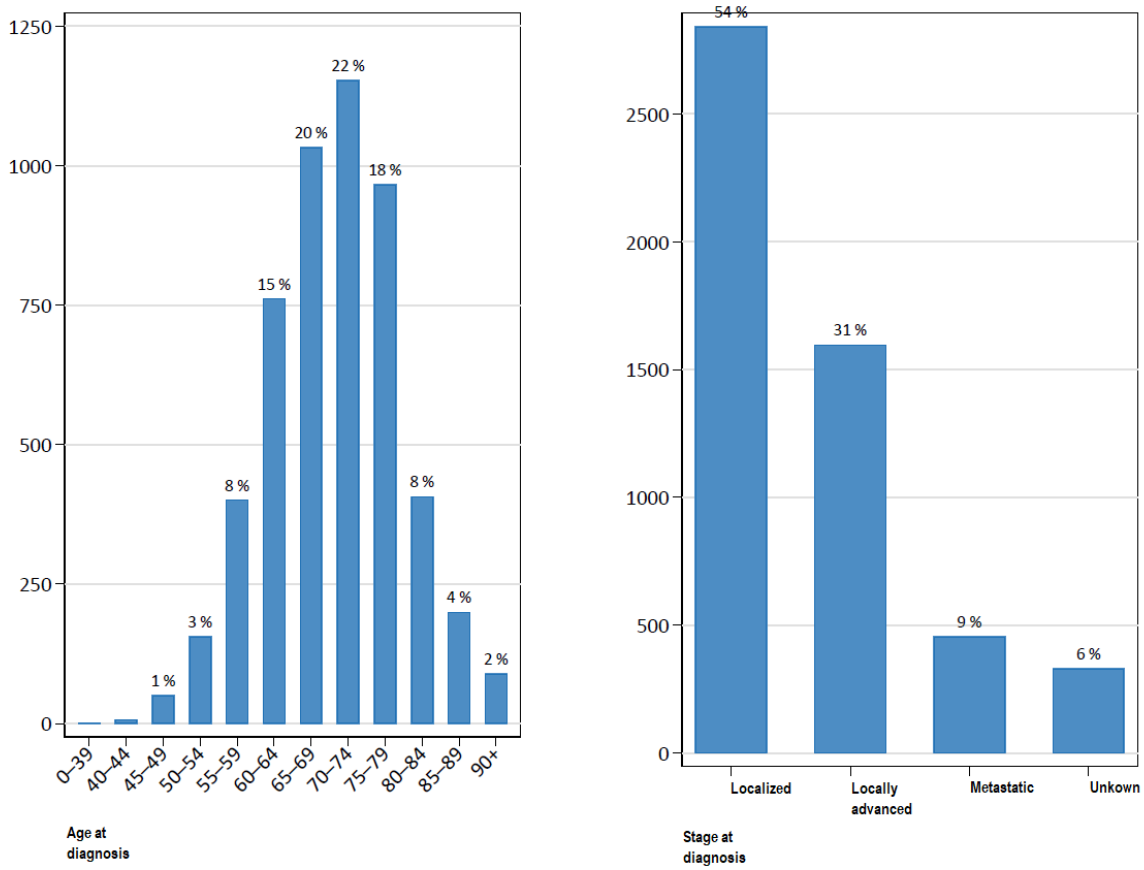
The motive for this work was to develop a local database for quality assurance and research. Furthermore, the aim was to avoid the need for multiple entries, to secure adherence and to include both patient-reported outcomes measures (PROMs) and patient-reported experience measures (PREMs). As these elements are then integrated with and become a part of the electronic medical record (EMR), the goal was to utilize the EMR for registration. In the scientific papers, the aim was to use selected information from the database to evaluate quality of care.

Incidence, prevalence and prognosis of prostate cancer

Prostate cancer is the most prevalent, non-skin, male cancer in high-income countries, and mostly affect men over sixty years of age [3]. In Norway, there are about 5000 new cases each

year, and in 2020, the incidence was 4999 cases with a mean age of about seventy years old [4]. Over the last decade the number of men living with prostate cancer in Norway has nearly doubled, from 32,022 in 2010 to 56,713 in 2020 [4]. The majority of patients are diagnosed with localized or locally advanced disease, the latter meaning that the cancer has broken through the prostate capsule and/or into adjacent tissue. Distant metastases are present in about 9% of patients (Figure 1). Patient prognosis depends on whether the disease is localized/locally advanced or metastatic and on tumor characteristics. Overall, the five-year relative survival rate is 98%, but with primary metastasis it is 31% [5]. In localized/locally advanced cancers, tumor characteristics determine cancer-specific survival. With favorable characteristics, the cancer may not affect patients' longevity; whereas with unfavorable characteristics, the five-year survival rate may be substantially poorer. In Norway there is an 86% five-year survival rate for men diagnosed between 2017 and 2021 [4]. Treatment also varies with the extent of disease. With localized or locally advanced disease, curative treatment with complete eradication of the cancer is possible. However in cases of distant metastases, treatment is palliative, aiming at prolonging life and relieving symptoms. Due to the slow natural course of prostate cancer, with its overall good prognosis, decision-making about which men to treat and which treatment to offer each individual is challenging. Since adverse effects after and during curative treatment could reduce quality of life and life-expectancy for these men is long, they risk living with adverse effects for many years. Hence, when aiming for the best possible treatment, an evaluation of the quality of care is paramount.

Figure 1: Age and stage at diagnosis in 2021 (Norway)



Source: Cancer Registry of Norway

Diagnostic work-up

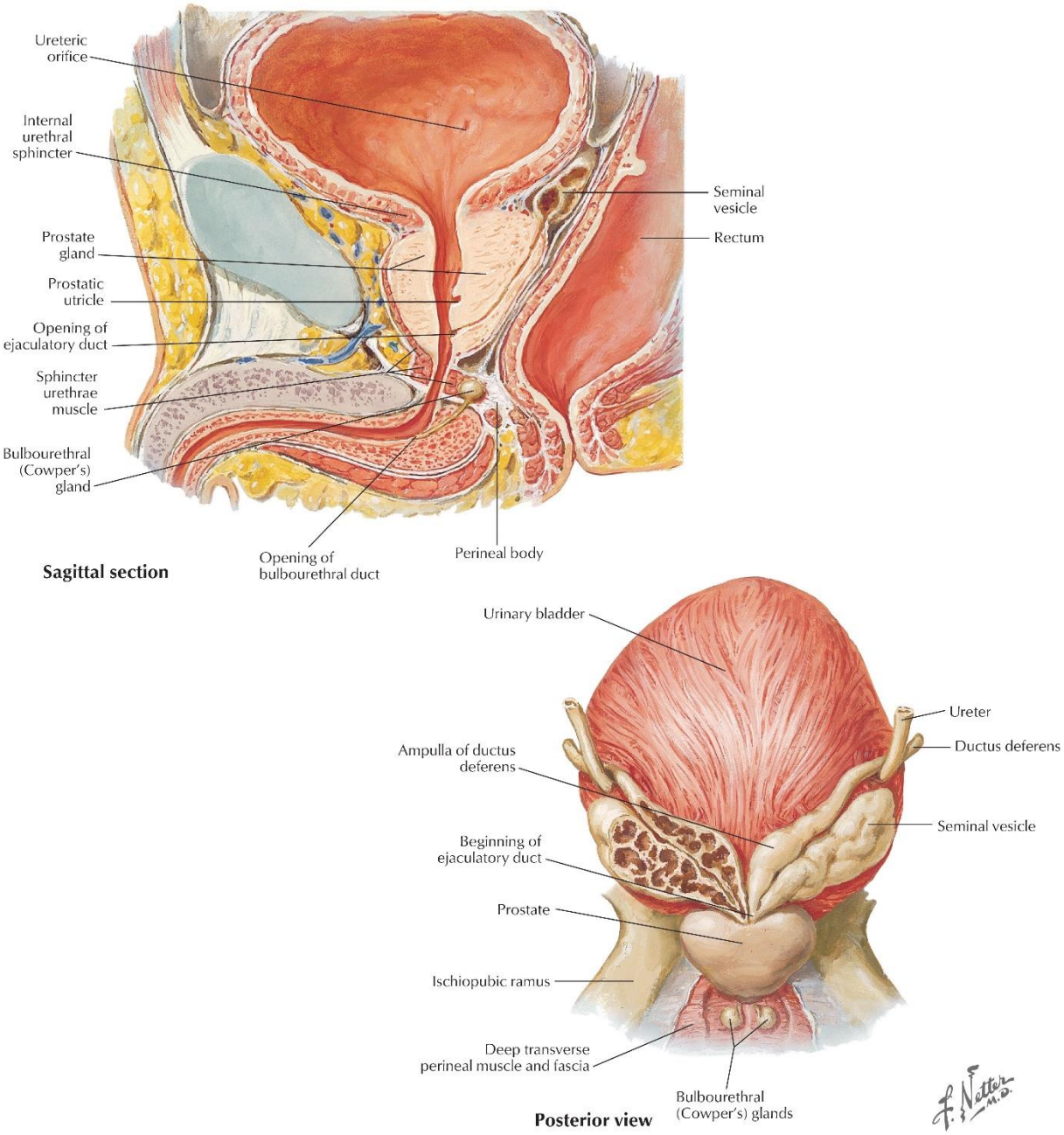
The aim of a diagnostic work-up is to provide all information necessary to select the most appropriate treatment for individual patients and enable conclusions regarding a patient's current cancer stage and risk for future cancer progression and metastases. A full urological work-up of patients referred to a urologist for a prostate cancer screening includes a clinical evaluation, biochemical parameters, a biopsy an MRI of the prostate gland, and eventually further imaging diagnostics if metastases are suspected, highly likely or present. The diagnostic pathway selected for individual patients may vary with age, clinical information, and comorbidity. Current age and comorbidity are determining factors in life expectancy. Considering the overall good prognosis of prostate cancer, radical treatment of localized/locally advanced cancer may not be appropriate if these competing mortality risks

overrule the risk of the cancer itself. Moreover, knowledge of metastases at the time of referral prevents curative treatment. Thus, work-up procedures that will have no treatment consequences for individual patients should be avoided.

Clinical and biochemical evaluation

The prostate gland is located in the pelvis and is an important reproductive organ. The apex of the prostate is anatomically close to the urethral sphincter (Figure 2), and there is a network of nerves responsible for erectile function on the prostatic surface. Although tissue changes in and adjacent to the prostatic gland may thus affect urinary and sexual function, early prostate cancer is normally asymptomatic [6]. In the aging male, lower urinary tract symptoms are prevalent, and it is not possible to distinguish symptoms due to benign prostate enlargement often resulting from other conditions [7].

Figure 2: Anatomy of the prostate



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Physical symptoms are therefore of little diagnostic value, and in all cases, assessment of prostate specific antigen (PSA) levels in the blood is the main diagnostic factor, which is eventually combined with digital rectal exploration. Clinical examination with digital rectal exploration provides information about the extent of the cancer, specifically whether it is confined to the organ or extends through the prostatic capsule. Suspicious findings of digital-

rectal exploration combined with an elevated PSA increase the risk of having prostate cancer [8]. PSA is found in prostatic tissue and is a widely used indicator of prostate cancer [9]. PSA became commercially available almost forty years ago [10]. Today PSA adds information to identify the men at risk for prostate cancer and determine which men to biopsy. There is no cut-off for a normal versus abnormal PSA [11]. A PSA below 4 ng/ml is often considered to be normal, but men with a PSA below 4 ng/ml are also at risk of having cancer. Cancer has been shown to be present in 27% of men with s PSA between 3.1–4.0 ng/mL [12]. Additionally, PSA increases with age, and the levels can vary among individuals . Furthermore, PSA is not cancer specific. High levels of PSA can be seen in men with urinary-tract infections, urinary retention and benign prostate enlargement. Generally speaking, however, high levels of PSA are associated with an increased risk of having prostate cancer [13, 14].

Because of its low sensitivity, PSA has weaknesses as a screening tool. With a cut-off level of 4.0 ng/ml, the sensitivity of detecting cancer is 21% according to a review [15]. Additionally, the specificity is 91%, and the positive predictive value is 30% [15]. The concern about PSA screening is the risk of overdiagnosis and secondary overtreatment [16-18]. On the other hand, PSA is an important marker after treatment with curative intent.

PSA density is defined as PSA divided by prostate volume, and it can provide additional information on which men to biopsy, especially when combined with MRI findings [19, 20].

Biopsy

In most cases a prostate cancer diagnosis is confirmed by prostatic biopsies. The exception is in men with comorbidity and a short life expectancy who have clinically obvious prostate cancer and for whom a biopsy may not be necessary.

Prostatic biopsies are performed with a transrectal or transperineal approach, which can be either systematic or targeted [21]. The transrectal approach was an early standard of care. With this approach, a biopsy, with or without anesthesia, was performed via the rectum either directly or as guided by ultrasound. Problems with transrectal biopsies included a higher rate of infection and the subsequent increased antibiotic resistance [22]. However, a recent single-center study from Germany showed that the infection rate after transrectal biopsies was acceptable, even in an area with a higher prevalence of resistant microbes [23] . The alternative is the transperineal technique, where the biopsy is performed by accessing the prostate through the skin of the perinium without entering the rectum. Observational data has shown that the transperineal approach is associated with lower infection rates [24-28]. Hence, transperineal biopsies are now recommended by the European Association of Urology [21]. Targeted biopsies, either ultrasound-guided or with a fusion technique where information from MRI is merged with an ultrasound, are now the preferred method [29].

When prostate cancer is confirmed by biopsy, the cancer is categorized as one of five different grades by the pathologist [30]. For many years, grading of prostate cancer was performed according to a system developed by Donald Gleason on a scale of Gleason score six to ten. In recent years, Gleason scores were replaced by five different grade groups [31]. The concordance between grade group, Gleason score and risk group is shown in the table below.

Gleason grade refers to the tissue architecture and gives information about the patient's prognosis [32, 33]. Low-grade prostate cancer consists of well-differentiated glandular structures similar to normal prostate glands. The score is calculated by combining the grades of the cancer cells in the two largest areas where cancer is found in the tissue. The scale ranges from 6 to 10, where a score of 6 is equivalent to low-grade cancer. The scale is continuous, and the cancer tissue becomes increasingly dissimilar to glands as its Gleason

score rises. For the highest Gleason score, the original architecture is unrecognizable, and the cells are poorly differentiated.

Men with low-grade cancer have a lower risk of progression and development of metastatic disease than men with high-grade cancer do [34]. In 2014, the grading system was revised, and Gleason scores were replaced with grade groups. Table 2 shows the concordance between grade group, Gleason score and risk group.

Table 2: Concordance between grade group, Gleason score and risk group

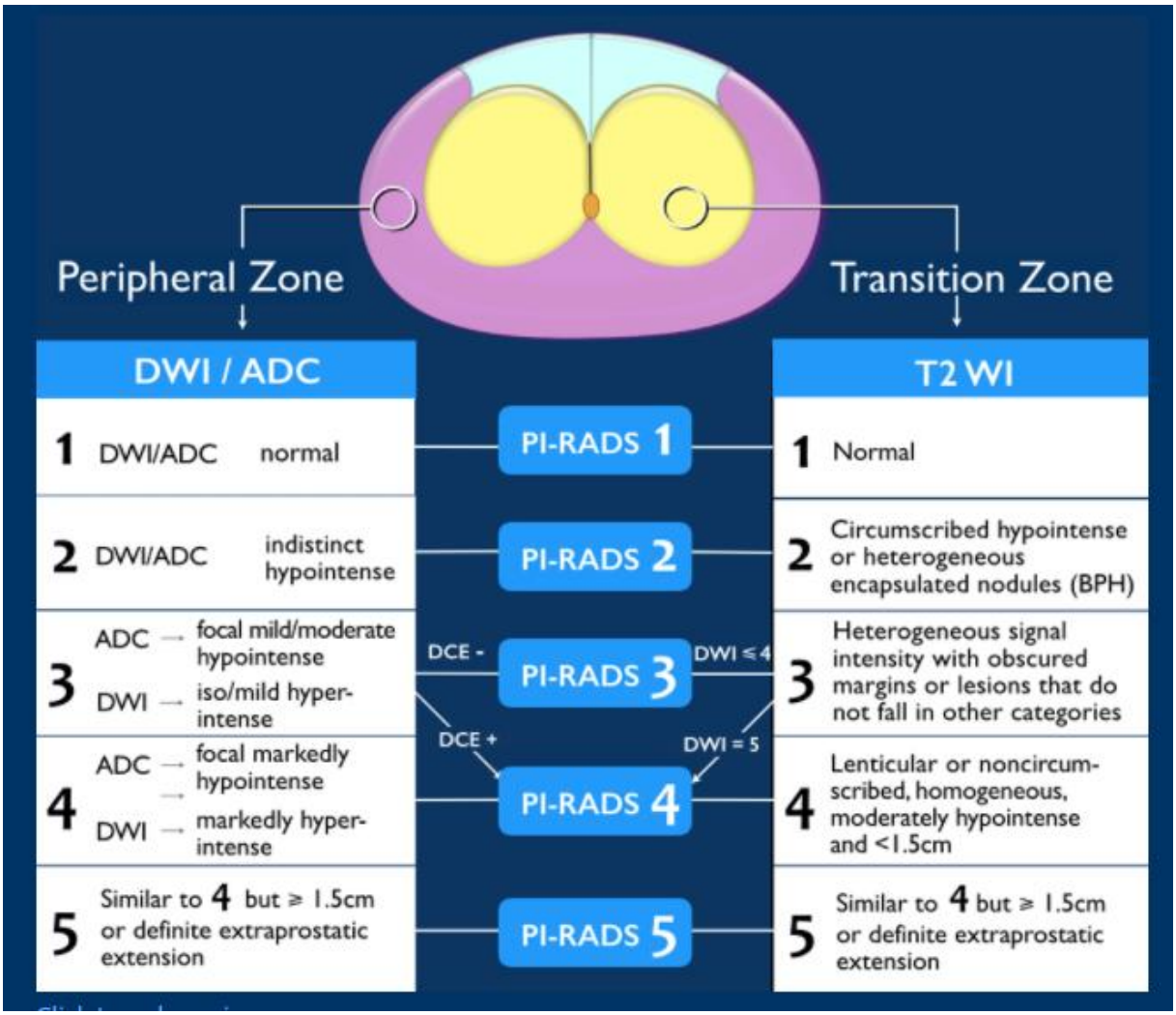
Grade group	Gleason score	Risk group
1	6	Low-risk
2	7 (3+4)	Intermediate risk
3	7 (4+3)	
4	8	High-risk
5	≥ 9	

Cancer detection with MRI

In recent years, MRI has gained popularity in prostate cancer diagnostics. Currently men eligible for treatment with curative intent undergo an MRI before biopsy [21, 35]. A prebiopsy MRI is likely to be cost-effective and findings on the MRI can contribute to deciding if a biopsy is necessary [21, 36, 37]. In cases of high comorbidity burdens, short life expectancies, and known primary metastatic disease, an MRI may not be necessary for treatment decisions and can therefore avoided. Lesions on MRI are categorized by Prostate Imaging Reporting and Data System (PI-RADS) [38, 39]. The scale goes from 1–5, where a PI-RADS score of one means that a clinically relevant prostate cancer is unlikely, and a PI-RADS score of five indicates a high probability for prostate cancer. Exactly how to define the probability of having prostate cancer with the different PI-RADS scores is difficult, due to the heterogeneity of study cohorts and inter-reader variability. However, a review of the current literature reports an 85% cancer detection rate in men with PI-RADS 5 lesions [40].

PI-RADS was developed by the American College of Radiology (ACR), the European Society of Uroradiology (ESUR), and the AdMetech Foundation to standardize the of findings of multiparametric MRIs (mpMRI) [38]. The system can also be applied to biparametric MRIs (bpMRI) [41, 42]. An mpMRI consists of T2 weighted images (T2 is a pulse sequence on an MRI), diffusion-weighted images and a dynamic contrast enhancement. BpMRI, a protocol without a dynamic contrast enhancement, costs less and takes less time [43] [44]. The detection rate of prostate cancer with bpMRI is comparable with mpMRI [42, 45, 46] despite the fact that omitting contrast reduces the accuracy of categorization of PI-RADS 3 lesions in the peripheral zone [43, 47].

Figure 3: Assessments of PI-RADS categories



DWI/ADC—diffusion weighted imaging/apparent diffusion coefficient; T2 WI—T2 weighted images; DCE—dynamic contrast enhancement

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Stages of prostate cancer

The TNM classification of malignant tumors published by the Union for International Cancer Control is regarded as the standard classification of a tumor's extent [48]. T describes the primary tumor, N the regional lymph node involvement and M the distant metastatic spread. The classification also distinguishes between the tumor's clinical (cT) and pathological (pT) stages determined by the pathology report after the surgical removal of the primary tumor.

Localized prostate cancers are stages T1–T2 cancer, i.e., located inside the prostatic gland, whereas locally advanced cancers are stages T3–T4 cancers extending through the prostatic capsule (Figure 4).

For prostate cancer, the pre-treatment stage is based only on clinical examination without additional imaging [49]. T-staging with MRI can provide additional information about the extent of the tumor. As available trials concerning disease management rely on clinical T-staging without imaging, the use of MRI for local staging will result in a shift from a risk group to a higher stage. This may in turn influence treatment decisions. If used for staging, it is not clear whether mpMRI would be superior to bpMRI for evaluating tumor growth through the capsule. However, bpMRI has a lower sensitivity for evaluating seminal vesical involvement as compared to mpMRI [50-52].

N- and M-stages occur after information from bone scans, CTs, MRIs or PET/CT scans is received. These methods are more sophisticated modalities for imaging as PET/CT have increased the detection rate of metastasis; however, the effect on survival and therapeutic benefits has yet to be shown [53].

Figure 4: Illustrations of different clinical stages of prostate cancer

T1: non-palpable tumor, T2: organ-confined, palpable tumor, T3: - palpable tumor with extracapsular extension and/or invasion of the seminal vesicle(s), T4: tumor is fixed or invades adjacent structures (other than seminal vesicles).

Used with permission of the American College of Surgeons, Chicago, Illinois. The original source for this information is the AJCC Cancer Staging System (2020).

Table 3: Clinical Tumor Node Metastasis (TNM) classification of prostate cancer

Primary tumor (T-stage is based on digital rectal exploration)	
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
	Non-palpable tumor
T1a	Incidental histological finding in < 5% of tissue resected
T1b	Incidental histological finding in > 5% of tissue resected
T1c	Tumor identified by needle biopsy
	Palpable and organ-confined tumor
T2a	Tumor involves one-half of one lobe or less
T2b	Tumor involves more than half of one lobe
T2c	Tumor involves both lobes
	Extension through the prostate capsule
T3a	Extracapsular extension
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal vesicles
	Regional lymph nodes
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Regional lymph node metastasis
	Distant metastasis
M0	No distant metastasis
M1	Distant metastasis
M1a	Non-regional lymph node(s)
M1b	Bone(s)
M1c	Other site(s) with or without bone disease

Risk stratification and treatment decisions

Treatment decisions are made after staging, and in case of distant metastases, palliative treatment will be offered.

Non-metastatic cancers are further stratified into three risk groups: low, intermediate, and high risk (Table 4) based on information about the presence of prostate specific antigen (PSA), the grade group and the tumor stage [21]. Although the overall ten-year-survival rate for non-metastatic disease is good, it varies considerably between risk groups [4]. Thus, treatment is individualized, depending on risk group (tumor characteristics), and also on patient factors including age, comorbidity and preference. Due to the good long-term survival rate in the absence of curative treatment [54], only men with a life expectancy of more than ten years are offered treatment with curative intent. For this group, the urologist must try to identify those who have a cancer that could progress or develop metastasis, equivalent to clinically significant cancer, as opposed to those who have an indolent and slowly progressing disease with good long-term prognosis, which is termed non-significant cancer.

There is no clear definition of the term clinically significant prostate cancer, but one common definition is that have a biopsy grade group greater than one [20]. If the concordance between grade group at biopsy and at prostatectomy were perfect, men with low-grade cancer would be advised not to have their cancer treated. However, a share of these men experience an upgrading of their cancer to a higher grade group at their prostatectomy.

The patient's age must be considered, but old age by itself is not a contraindication for curative treatment [55] as the top 25th percentile of eighty-year-old men are expected to live for more than ten years. However, older men are reportedly at higher risk of under-treatment in cases of high-risk cancer [56, 57]. High-risk disease is associated with poorer prognosis, not only in terms of survival, but also in terms of experiencing symptom distress. The prevention of local symptoms and symptoms secondary to metastasis is the main treatment goal for these older men. Aging is also associated with increasing prevalence of health problems that may increase the risk of side effects while undergoing treatment. In order to select those who are suitable for treatment and are most likely to benefit from it, it is therefore

recommended that men over seventy years of age be screened with Geriatric 8 (G8) [58]. G8 is a tool developed to screen for frailty, i.e., increased vulnerability to stressors in older patients with cancer [59]. G8 screening can identify frequently occurring geriatric problems and patients at risk for functional decline [60, 61] . The European Association of Urology recommends that G8 should be combined with mini-COG to assess cognitive function. Other patient factors such as comorbidity and patient preference are also indicators of the best choice for treatment [62, 63]. Patients with a high probability of dying of other causes should not be offered radical treatment.

Table 4: EAU risk groups for biochemical recurrence of localized and locally advanced prostate cancer

Risk-groups			
Low risk	**Intermediate risk**	**High risk**	
PSA < 10 ng/mL and Grade group 1 and cT1-2a	PSA 10–20 ng/mL or Grade group 2/3 or cT2b	PSA > 20 ng/mL or Grade group 4/5 or cT2c	any PSA any Grade group cT3–4 or cN+
Localized			**Locally advanced**

Treatment of prostate cancer

There are different alternatives for treatment with curative intent (radical treatment), but only surgery or radiotherapy are established options [21]. Other alternatives, for instance high intensity focused ultrasound (HIFU), have shown promising results, but more research is still needed to determine if they are as effective as surgery and/or radiation therapy [64, 65]. Radical treatment options besides surgery or radiotherapy should not be offered outside clinical trials [21].

Active surveillance is the preferred option for men with low-risk cancer [21]. Active surveillance involves a systematic follow-up program including the repeated monitoring of

PSA, biopsies and MRIs. If there are signs of cancer progression during these follow-up sessions, patients are advised to undergo radical treatment. The rationale behind active surveillance is to leave men with a favorable prognosis untreated so as to reduce overtreatment.

For men with intermediate- and high-risk cancers, radiotherapy and/or surgery are established treatment alternatives. Both options are regarded as equally effective, but both have unpleasant adverse effects [66].

The basic principle of radiotherapy is using ionizing radiation to destroy cancer cells. Radiotherapy for prostate cancer is often combined with endocrine therapy upfront and may be administered as external beam irradiation or brachytherapy. The latter involves internal radiation where the source of the radiation is placed in the prostate gland.

External beam irradiation is the standard in Norway. The most common adverse effects are secondary to the toxicity of ionizing radiation: urinary and bowel urgency, diarrhea and rectal bleeding. There is also an increased risk of developing bladder cancer after prostate radiotherapy [67].

Surgical treatment with curative intent for prostate cancer involves the removal of the entire prostate gland. Due to the local anatomy (Figure 2), the procedure involves the risk of damaging the urethral sphincter, which could cause urinary incontinence. Also, if the network of nerves responsible for erectile function is not preserved, sexual function will be affected.

In accordance with patient preferences, a nerve-sparing surgical procedure is normally an option if the tumor is localized to the prostate without the involvement of the prostate capsule. In addition to a radical prostatectomy, and for diagnostic and possibly therapeutic purposes, the lymphatic glands of the pelvis are also removed in patients with high-risk disease. The standard procedure for a radical prostatectomy in Norway is now a robotic-assisted radical

prostatectomy (RARP). There is no proven oncological benefit for robotic surgery as compared to traditional surgery, but patients treated with robotic surgery have fewer short-term complications and shorter hospital stays [68]. However, as compared to traditional surgery, RARP has the long-term adverse risks of urinary incontinence and sexual dysfunction that could be bothersome and reduce quality of life [66].

Urinary incontinence, depending on definition, affects around 20% of RARP patients [68]. Erectile dysfunction is somewhat more difficult to investigate as the prevalence of erectile dysfunction increases with age in men regardless of prostate cancer. Nevertheless, the Europa Uomo Patient Reported Outcome Study (EUPROMS), found that sexual dysfunction was the adverse effect that affected quality of life most severely. In this study 54.5% reported that erectile dysfunction was a moderate or big problem after a radical prostatectomy, and 44.5% reported the same after radiotherapy [69]

Men with local or localized prostate cancer who are not eligible for radical treatment, mainly elderly patients with comorbidity and patients with shorter life expectancies, are advised to watch and wait, in other words to delay treatment until symptoms occur (if they do).

For metastatic prostate cancer, the main treatment goal aim is life prolongation and palliation. Life-long endocrine therapy is the cornerstone of treatment aimed at reducing testosterone levels or testosterone effects. Systemic endocrine therapy works in two different ways: either by medical castration (medication that reduces testosterone levels) or by blocking cellular testosterone receptors. Surgical removement of the testes is an alternative to medical castration.

Additionally, in recent years systemic treatment has evolved quickly and oncologists have several lines of additional treatments available. Chemotherapy (docetaxel/cabazitaxel), both as a primary and a secondary/cycling treatment option, and several lines of endocrine therapy

(abiraterone/enzalutamide/darolutamide/apalutamide) are in use and have improved survival rates, especially when used upfront in metastatic disease. Furthermore, other drugs, including Radium-223, are used to treat bone metastases.

Treatment challenges

A challenge in all prostate cancer treatments is selecting the right treatment for each individual. For patients with prostate cancer, overtreatment of low-risk disease and undertreatment of high-risk disease are specific concerns. The current tools for risk stratification and diagnostics have weaknesses, and providers lack the necessary tools for precise risk stratification and patient selection.

To avoid overtreatment, it is important to start with who is biopsied. Screening and following biopsies can lead the detection of low-grade and non-significant cancer [18]. Findings from MRIs, combined with clinical information, such as PSA density and comorbidity, are used to select which men are at risk of having a clinical significant cancer and are recommended to undergo biopsies [20, 70].

If low-risk prostate cancer is diagnosed, active surveillance is recommended. A challenge of active surveillance is the psychological burden of having an untreated cancer [71]. Additionally, men undergoing active surveillance are at risk of harboring significant cancer despite biopsy results showing the opposite. A population-based study found that 21% of men on active surveillance experienced upgrading at prostatectomy; a single-center study founded that 49.3% had their cancer upgraded with 12.5% upstaged to T3 [72, 73].

From a clinical point of view regarding treatment advice, it is important to identify predictors of upgrading, especially for men with low-grade and low-risk cancer. If the probability of upgrading at a prostatectomy is high, i.e., the patient is at high risk of having a cancer with a

higher risk profile than presumed, they should be so informed before choosing active surveillance. PSA density is a known predictor of upgrading [74-77].

There is evidence that an MRI combined with specific biopsy techniques increases the diagnostic precision. When specimens from prostatectomies were compared to grade groups during the biopsy stage, the upgrade rate was 42.7% after systematic biopsies and 23.3% after targeted biopsies [78]. The chance of downgrading was also found to be higher after systematic biopsies. The authors of this meta-analysis concluded that MRI-targeted biopsies are more precise than systematic biopsies. Information from MRIs, such as PI-RADS score, has been shown to be an independent predictor of upgrading from biopsy to radical prostatectomy [79]. Studies on upgrading are mostly based on mpMRIs, and one of the aims of this thesis was to investigate whether information from bpMRIs is also of clinical importance.

Undertreatment is also a concern in the treatment of prostate cancer. Life-expectancy and comorbidity, not just age alone, should be decisive factors when considering whether or not to offer treatment. A large share of men older than seventy are healthy and expected to live for more than ten years after diagnosis, and these men should receive treatment if diagnosed with a high-risk cancer [56].

After diagnosis, decisions about treatment should be made with the patients. In many ways, prostate cancer treatment is a pedagogical challenge. It is demanding to make the relevant information understood. In a population-based sample of men recently treated with either surgery or radiotherapy, no more than one-third had adequate knowledge about the long-term adverse effects [80]. Once diagnosed with cancer, the first concern for many patients is to be cured. The rationale behind active surveillance and the recommendation of delayed treatment might be difficult to understand. Due to psychological factors, men eligible for active surveillance may choose radical treatment instead [81]. Web-based tools for decision-making

and patient decision aids might contribute to ensuring that patients feel involved and receive sufficient information [82]. In a randomized controlled trial, a patient decision aid increased the patients' knowledge, but this did not significantly impact decision making [83]. It has also been found that better knowledge about the consequences of treatment is associated with higher patient satisfaction but also with more decision difficulties [84]. Understandable, sufficient information is a cornerstone of patient-centered care. To date, there is limited research on how to measure this aspect of quality of care for prostate cancer patients.

Quality and quality indicators

The general term "quality" is abstract and multidimensional. From a philosophic point of view quality is sometimes stated as obvious but not possible to define. According to the Oxford Learner's Dictionary, one way to define quality is "the standard of something when it is compared to other things like it or how good or bad something is" [85]. Consequently, the term "quality" is relative. As such, quality is also linked to expectations [86]. How a person assesses the quality of a thing or experience depends on what he/she expects. Another aspect of quality is subjectivity. Even with quite similar expectations, experiences and perceived quality could be rated differently by each individual [86].

Similar to the general term, it is difficult to define what quality means in healthcare. Quality includes how good or bad the provided care is [87], but the perception of what quality is depends on individual perspective [88]. From a patients' point of view, quality of care has a different meaning than it does for healthcare workers, health authorities and politicians. Since its definition is vague, measuring quality can be quite taxing.

In healthcare, quality is often described with dimensions or measured indirectly with indicators [89, 90]. In this vein, the World Health Organization has published seven dimensions that are necessary for determining the quality of healthcare; namely, health

services should be effective, safe, patient-centered, timely, equitable, integrated and efficient [89]. Another way to measure quality in healthcare is to do so indirectly with a triad of indicators, as introduced by Donabedian, a pioneer in the field [90]. He outlined structure indicators, process indicators and outcome indicators for quality measurements. An example of a structure indicator is the staff's competence and qualifications. Other examples are the hospitals' facilities (for instance number of beds) and medical equipment. Process indicators refer to the patient's experience and the staff's adherence to guidelines. How patients rate and perceive the quality of communication about adverse effects is an example of a process indicator. Examples of outcome indicators include the consequences of care, such as thirty-day mortality and adverse effects after surgery. Patient satisfaction is also considered to be an outcome measure [91]. Administrative, clinical and patient-reported data are the sources used to measure quality indicators.

Patient-reported data and quality of care

Patient-reported data are essential for capturing the patients' perspective. They are divided into Patient-reported Experience Measures (PREMs), measures of satisfaction and Patient-reported Outcome Measures (PROMs). PREMs measure the patient's experience (for instance, quality of communication and involvement in decision-making) and satisfaction about how the provided care met their expectations. According to Donabedian's model, PREMs are process measures, while satisfaction is an outcome measure. They are, however, linked to each other [92]. Expectations can affect the experience, and experience can affect satisfaction [91]. PREMs are further divided into relational measures (communication and interaction with health care workers) or functional measures (available facilities) [93]. Being process measures, PREMs can help researchers evaluate quality of care, make comparison between institutions and capture changes over time. The third category of patient-reported data, PROMs, measure how patients perceive their health or symptoms. In conclusion,

patient-reported data are important process indicators and outcome indicators. Applying a framework for quality improvement provided by The National Health Service (NHS) in the United Kingdom, which includes clinical effectiveness, safety and patient experience [94], PROMs evaluate effectiveness and safety, while PREMs evaluate patient experience. In other words, PREMs are experience measures, while PROMs and satisfaction are outcome measures. For evaluation of quality of care, process measures are in many ways more precise than outcome measures as they are less prone to differences caused by how data are captured and/or patient-cohorts [95].

Validation of tools for patient-reported data

When choosing a tool for patient-reported data, it is necessary to make sure that it will provide trustworthy answers. The evaluation of self-reported questionnaires is complex. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) has developed criteria to evaluate PROM questionnaires. A properly tested questionnaire should be reliable, valid and responsive. Each of these criteria contains one or more measurement properties [96]. Reliability refers to the consistency of the instrument. For example, if a questionnaire is designed to measure quality of life and a patient's quality of life is stable, the questionnaire will be reliable if the scores are the same when filled-out on different occasions. Validity refers to the degree to which a questionnaire measures what it is designed to measure. This criterion can be further divided into content validity, construct validity and criterion validity. Content validity is defined as how an instrument measures all aspects of the content. In other words, a questionnaire must contain all relevant parts in order to provide valid results. For instance, it is crucial that a PROM questionnaire constructed to evaluate symptoms for prostate cancer patients contains items regarding both urinary and sexual symptoms. Items in a questionnaire with good content validity are relevant, comprehensive and understandable [97]. Construct validity is based on the necessity of

adequate content validity. The question is whether the questionnaire really measures what it is supposed to. PROMs (and PREMs) are often constructed with dimensions that cover different aspects of the measured matter, and the internal structure reflects how the dimensions and items in each domain are related.

Criterion validity is used when a tool is evaluated against a gold standard. This means that new questionnaire should be tested and monitored alongside existing, validated questionnaires.

Finally, responsiveness is the likelihood of a questionnaire to detect changes over time.

The COSMIN protocol also applies to PREMs [98].

Patient-reported experience measures (PREMs)

PREMs are relatively new measures and are often missing from clinical registries. Despite being relatively new, there are several PREMs available. Examples of existing PREMs are the surveys developed by the Picker Institute and the Consumer Assessment of Healthcare Providers (CAHPS), and both have questionnaires adapted to patients with cancer. The Picker Institute has worked with patient-centered care for years, and in the U.K., their National Cancer Experience survey is now recommended and used for cancer patients [99]. In the U.S., some of the CAPHS surveys are administered by the government (Department of Health and Human Services) as part of their public reporting [100]. A systematic review identified two experience measures developed in Norway [101]: the Patient Experience Questionnaire (PEQ), initially developed to measure patient experiences in primary healthcare and the Norwegian Patient Experience Questionnaire (NORPEQ) [102, 103]. The PEQ was revalidated in 2021 in a study of over 4,000 participants from different hospitals in Norway. One reason for this was that the statistical approaches in the field of psychometrics has evolved in recent years. The authors identified weaknesses in the PEQ and suggested

adjustments to the questionnaire [104]. In Sweden and Norway, another existing PREMs is a survey called, Quality from the Patient's Perspective (QPP). The QPP has a scientific basis, having been developed after qualitative patient interviews. The questionnaire has previously been used in other settings and applied to other group of patients [105-107].

Due to the large number of existing PREMs, there is a diversity in content and how they are validated, resulting in many existing PREMs lacking proper validation [108]. Thus, choosing an appropriate PREM for each group of patients is challenging.

Assessment of quality and patient-reported data for RARP patients

A standard and uniform way to assess quality of care for prostate cancer patients does not exist. Based on Donabedian's model, a suggestion of twelve quality indicators selected by an international panel has been published [109]. The number of patients treated per year was the only structure indicator. Proposed process indicators were as follows: rate of positive margins after radical prostatectomy, PSA level at diagnosis, documentation of clinical T-stage, active surveillance or watch-and-wait status for men with low-risk disease, evidence that patients with high-risk disease received active treatment and time from diagnosis to first treatment. Positive margins refers to cancer cells at the edge of the tissue. Suggested outcome measures were 5-, 10- and 15-year overall survival rates, including clinical and/or biochemical disease-free survival rates after primary radical treatment; patient-reported urinary, sexual and bowel function; patient-reported urinary, sexual and bowel problems and rate of death from surgical complications.

The term "trifecta" has commonly been used to evaluate quality after radical prostatectomy, and consists of a good oncological outcome, urinary continence and erectile function [110]. Since, there is no standard definition of "trifecta" in the literature, a systematic review suggests the following consensus definition: freedom from biochemical recurrence, defined as

a confirmed (by two measurements) PSA > 0.2 ng/mL, preserved erectile function sufficient for intercourse with or without oral medication, and urinary continence as marked by wearing no pads [110].

If the rate of surgical margins and short-term complications is added to the "trifecta," the term becomes "pentafecta." A negative surgical margin is stated to be one of the established quality indicators after a radical prostatectomy [111], but it has weaknesses [112] . Although positive surgical margins are associated with an increased risk of biochemical recurrence, an impact on survival for patients with minimal positive surgical margins has not been shown [112]. The international panel included the rate of procedure-related death as an outcome measurement for short-term complications [109]. However, procedure-related death after RARP seldom occurs [113], and on an institutional level, registration of other short-term complications is more meaningful and provides important information for quality assurance. Short-term complications are measured in different ways. Notable and Trackable Event for Surgery (NOTES) is a system to register complications after RARP and was developed by the collaborative for quality improvement in the state of Michigan [114]. In NOTES, readmission is a one of the measures for short-term complications. As the majority of RARP patients are discharged the day after surgery, readmission could be a reliable and objective measure for perioperative complications. All the suggested NOTES measurements are easy to record.

In the definition of "trifecta," the oncological endpoint is defined as PSA relapse. One third of the patients will have experienced biochemical recurrence ten years after surgery. Biochemical recurrence, however, is not equivalent to clinical recurrence. The share of men who experience biochemical recurrence depends highly on the risk group, and this must be kept in mind if recurrence rates are used as a benchmark.

Erectile function and urinary continence are denoted as functional outcome measures and should be patient-reported to ensure reliable data. Surgeons tend to underestimate adverse

effects [115]. The Expanded Prostate Cancer Index Composite (EPIC) is a commonly used PROM questionnaire for prostate-cancer patients, and the twenty-six-item EPIC-26 is recommended by the International Consortium for Health Outcome Measurement (ICHOM) [111]. The EPIC questionnaires exist in different, compatible versions and are translated into several languages [116] . The shortest version is the sixteen-item Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) [117]. The questionnaire covers different aspects of adverse effects after treatment for prostate cancer including symptoms from the urinary tract, reproductive system, and gastro-intestinal system as well as fatigue and overall well-being. Patient-reported experience measures, which are important for patient-centered care, are used to a lesser degree to evaluate the quality of care for prostate cancer patients. There is no standard PREM questionnaire for prostate cancer patients.

Types of clinical registries

Clinical registries are designed to systematically collect clinical data and other health-related information. They are used to measure quality and to determine benchmarks [118, 119].

There are two main types of registries: institutional or population-based [120]. Institutional registries are either single registries or clusters of registries from different hospitals. The perfect clinical registry does not exist. Institutional and population-based registries have different weaknesses, strengths and objectives. The primary goals for hospital registries are quality control, education, research, and performance feedback [121]. Population-based registries provide information about incidence, mortality, adherence to guidelines, trends in treatment and variation in treatment and diagnostics between regions [122]. In other words, registries can give information about process and outcome measures. Examples of population-based registries are the Survival Epidemiology and End Results (SEER) database and the Cancer Registry of Norway [123]. Patient-reported data is, however, often lacking in clinical

registries [124]. Additionally, it is important that both baseline data and follow-up data are as complete as possible to provide reliable information.

A review of existing prostate cancer registries refers both to population-based and prospective patient registries [125]. Population-based prostate cancer registries collect data from patients diagnosed with prostate cancer, whereas a patient registry, for instance, enrolls patients with the procedure code for RARP. The Cancer Registry of Norway is an example of a population-based prostate cancer registry and provides excellent epidemiological information. A weakness of this registry is the capture rate of clinical data and limited follow-up data. In 2020, the completeness of clinical data at the time of diagnosis was 91.2%, for men who had had a radical prostatectomy 97.8% and radiotherapy 39.6% [4].
In Norway, all the national registries are evaluated annually. One of the requirements is a high degree of data completeness including whether patient-reported data is a part of the registries. The national prostate cancer registry has recently included patient-reported outcomes and experiences, but the response rate has been low.

In the U.S., one must apply to the Centers for Medicare & Medicaid Services (CMS) to qualify as a clinical data registry. One of the requirements of becoming a qualified clinical data registry is that the registry must contain performance measures and that data is collected from a minimum of twenty-five providers [126]. There are four qualified clinical data registries in urology in the U.S.: the Michigan Urological Surgery Improvement Collaborative, the American Urological Association Quality Registry, the AUGS Urogynecology Quality Registry and IntrinsiQ Specialty Solutions [126]. All four registries include different process measures and outcome measures. Two of them collect data manually; the other two collect data from the EMR. Only one of them includes patient experiences (IntrinsiQ Specialty Solutions).

Institutional prostate cancer registries enroll patients on the basis of diagnosis or procedure codes. The database considered by the current thesis includes patients treated with procedure code KEC01 for RARP. Local systems have the potential to increase the capture rate of both clinical and patient-reported data, at both baseline and follow-up.

F: Thesis aims

Aims

The overall topic of this thesis is quality assurance of the radical prostatectomy process. The main aim is to develop a local database to realize this purpose and investigate the validity and utility of selected database components to further improve the database and thus the quality of care for RARP patients. Hence, each sub-paper uses the local database as its source of information. The sub-aims were the following:

Paper 1: To describe the structure of a local database integrated in the EMR, focusing on how data are captured and used in a clinical environment.

Paper 2: To test the construct validity of an adapted version of the PREM questionnaire, QPP, for RARP patients.

Paper 3: To investigate the association between perceived quality of information about and help with adverse effects and patient-reported symptoms before and after a radical prostatectomy.

Paper 4: To identify predictors of histological upgrading in men with low-grade prostate cancer during a radical prostatectomy after a pre-operative biparametric MRI.

G: Materials and methods

Study design

Robotic surgery was introduced at Innlandet Hospital Trust in 2014, and since this time we have been developing a code-driven database to prospectively collect data for quality control. Before robotic surgery was introduced and became the standard procedure, radical prostatectomies were performed with an open technique. However, procedures for systematic quality assurance had not yet been established. Since 2014, the database has been revised and further developed several times. In 2017, an adapted version of the QPP became a part of the database. The research design of the different sub-works of this thesis were as follows:

Paper 1

Description of the idea and basic construct of the database (no study design).

Paper 2

A cross-sectional observational study to test an adapted version of the QPP for RARP patients.

Paper 3

An observational study evaluating the associations between patient-reported symptoms and the quality of information about adverse effects resulting in help with adverse effects.

Paper 4

An observational study on clinical data collected using the database including predictors of histological upgrading at prostatectomy in men with low-grade cancer.

Patients

The patients involved in the studies were all enrolled in the database developed for RARP patients. If accepted for RARP, they were routinely informed about the database when meeting with providers to receive information about the surgical procedure, predictable adverse effects and their expected post-operative recovery plan. These patients were then entered into the database if they provided their informed consent. A fluent understanding of the Norwegian language was a prerequisite to providing consent.

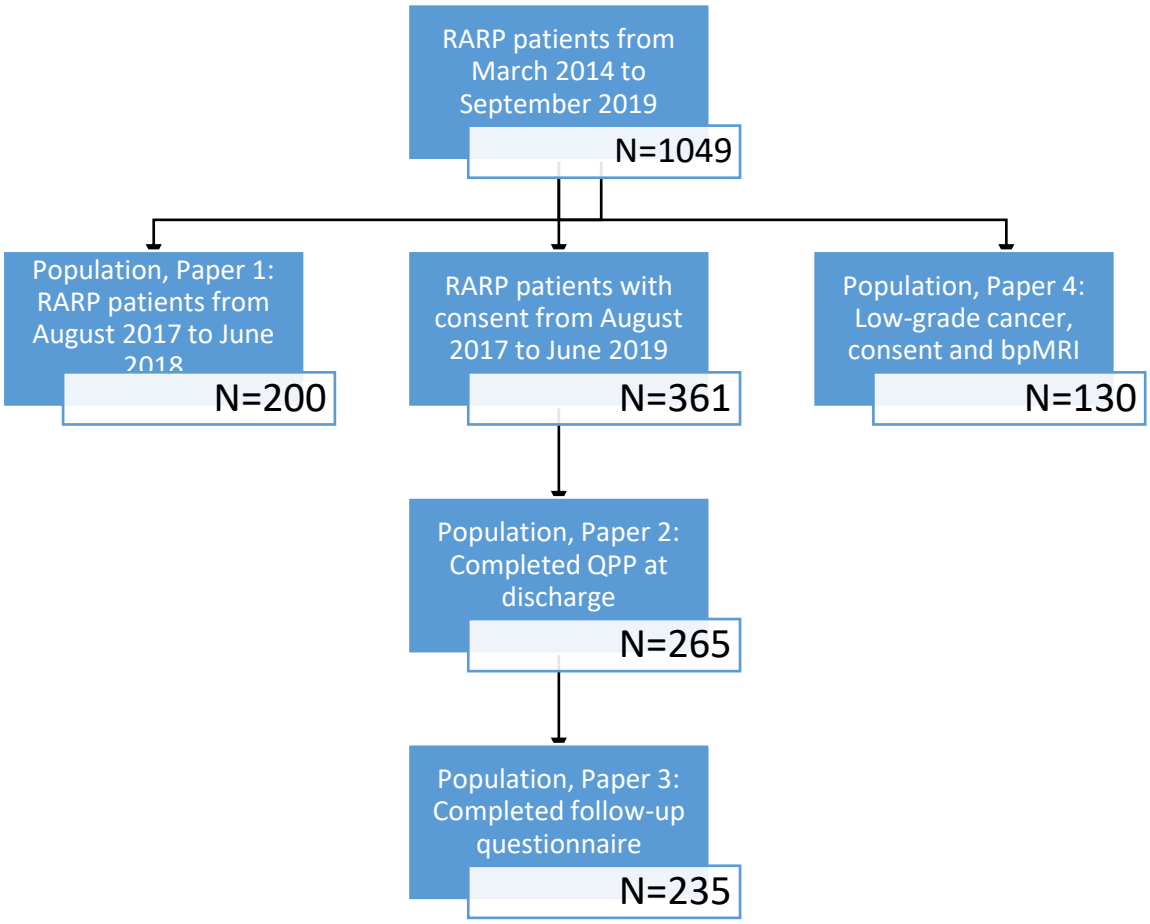
In Paper 1, the study population consisted of 200 men added to the database from August 2017 to June 2018.

The study populations in Papers 2 and 3 were added to the database between August 2017 and June 2019. In this period 361 gave their consent to participate. In Paper 2, 265 (73.4%) completed the QPP and constituted the final study population.

The eligible study population for Paper 3 was 265 men with baseline data and consent, who enrolled from August 2017 to June 2019. Of these, 235 (89%) had filled in a follow-up entry between twenty and forty-two months after surgery and comprised the final study population.

In Paper 4, all men enrolled in the database from March 2014 to September 2019 with low-grade cancer (grade group 1) based on a diagnostic biopsy and a pretreatment biparametric MRI performed at our institution and having provided their consent were eligible for participation. A total of 130 out of 1049 met the criteria for inclusion.

Figure 5: Flowchart of the study population in each paper



The database—Overarching structure

The database includes administrative, clinical and patient-reported data. It is stored on a secure server with the same level of security as the patients' EMRs. In order to gain access to the database, a password and permission from the hospital's data protection officer is required. Transmission of administrative and clinical data from the EMR is automatic and initiated by the code for RARP (KEC01). Administrative information, e.g., as age and date of surgery, are transferred when the code is registered. Clinical data are registered using structured forms (XML-files), composed of boxes and drop-down menus. After the forms are completed and approved, the clinical data are transferred to the database. Thus, information about all patients with the registered code KEC01 is available when the database is updated,

and the structured forms serve as documentation for both the EMR and registration. Patient-reported data is not a part of the EMR and were collected by questionnaire using a web-based system developed by the Information Technology department at Innlandet Hospital Trust. The questionnaires were either completed on an iPad (at the hospital/during consultations) or through a link sent to the patients in a follow-up email. The method and security of the web-based collection of patient-reported data was approved by the data protection officer at Innlandet Hospital Trust. The whole process of collecting data was closely linked to the clinicians' workflow. The different structured forms and patient-reported data were completed during the patient's journey from the first consultation through the hospital stay and over the course of the follow-up period (Figure 6).

Clinical data

In order to collect clinical data, three different structured forms were initially developed: one to register clinical data before surgery and additional information at the time of surgery, one for the histology report and one for follow-up. At the date of the surgery, information about the risk group (PSA, histological grade of biopsy, tumor stage) and the surgical procedure were registered. Table 5 provides information about the collected administrative and clinical data. In the first version of the forms (published in Paper 1), the histological grade was noted using the Gleason score rather than the grade group. Additionally, the T-stage was set after the combination of the clinical examination and the MRI findings. BpMRI was performed with 1.5 Tesla Achieva without an endorectal coil. The MRIs were classified according to PIRADS. For Paper 4, the tumor stage determined by MRI was reevaluated and reclassified by an experienced uro-radiologist, and PSA density was estimated using pre-treatment PSA and MRI measures. At follow up, documentation included information about PSA, complications and possible additional treatment. Complications were registered with the system developed by the MUSIC collaboration for quality improvement in Michigan [114].

Table 5: Administrative and clinical data included in the database

Measure	Details	Timing	Source
Treatment			
Robot-assisted radical prostatectomy	Nerve sparing or non-nerve sparing/Extended lymph node dissection (yes/no)/Drain (yes/no)/EBL/Time spent at surgery	By the time of surgery	Structured form (Form 1)[1] completed by the surgeon
Baseline characteristics			
Age		Prior to surgery	Administrative data[2]
Body Mass Index	Height and weight	Prior to surgery	Structured form (Form 1)[1] completed by the surgeon
ASA score[3]			
PSA			
Clinical stage	cT[4] (DRE/MRI)		
MRI	PIRAD score[5]		
Gleason score, pre-treatment biopsy	Highest Gleason grade		
Margin status	If positive: extension in mm, localization and Gleason score	Following surgery	Structured form (Form 2)[1] completed by a secretary using the pathology report
Gleason score, prostatectomy	Highest grade		
Pathological stage	pT		
Complications			
NOTES		At six weeks after surgery	Structured forms: Form 1 and 3[1]

Survival/disease control				
	Overall survival			Administrative data [2]
	Biochemical recurrence	PSA	At six weeks and three and twelve months after surgery	Structured form (Form 3)[1] completed by a registered nurse

[1] The structured forms (Forms 1–3) are integrated into the patients' electronic medical record, and the data are automatically transferred to the database localized on a secure server;

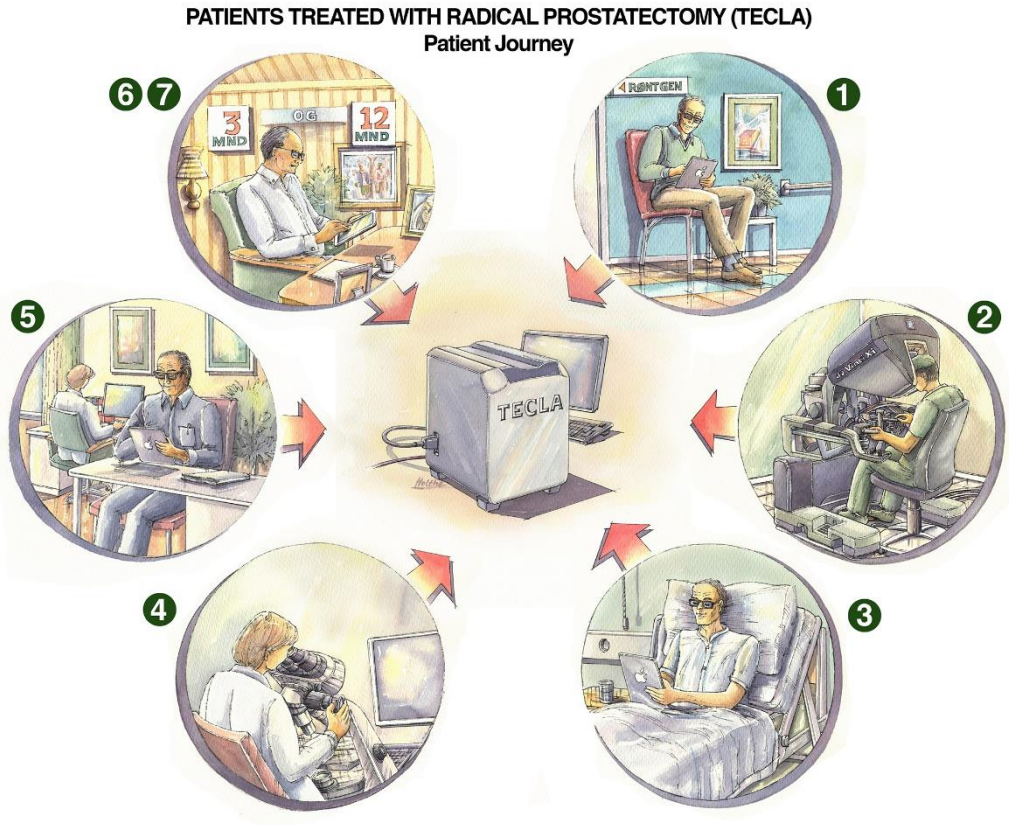
[2] Administrative data, automatically extracted from the patients' electronical medical record;

[3] ASA score = The American Society of Anesthesiologist Classification;

[4] Clinical staging based on digital rectal examination (DRE) and Magnetic Resonance Imaging (MRI);

[5] PIRADS = Prostate Imaging Reporting and Data System

Figure 6: Illustration of how data are collected during the patient journey



Data is imported in seven different steps: (1) Electronic documentation of opt-in consent prior to surgery and baseline EPIC-CP is provided, (2) Registration of clinical data is input at the time of surgery, (3) A QPP is completed by the patient before being discharged from the hospital after surgery, (4) Pathology report, (5) Follow-up after six weeks, (6, 7) EPIC-CP at three and twelve months and QPP after twelve months.

Patient-reported data

In the first version of the database, patient-reported data only included PROMs collected using an EPIC-CP at baseline and at follow-up. The EPIC-CP is a sixteen-item questionnaire where fifteen items assess five different domains of patient-reported symptoms: urinary incontinence, urinary irritation/obstruction, bowel symptoms, sexual symptoms and vitality/hormonal symptoms. Each item is answered on a Likert scale from 0–4, and each domain contains three items. Hence, each domain has maximum score of twelve, and the total EPIC-CP has a maximum score of 60. Higher scores indicate more symptoms. From August

2017, a QPP was added to the database, and routinely filled out. The QPP was completed after surgery but before discharge, i.e., in hospital. For Paper 3, a follow-up questionnaire consisting of an EPIC-CP and selected items from the adapted QPP was filled out between 20–42 months after surgery.

Quality from the Patient's Perspective (QPP)

As there is no generally-agreed-upon PREM used for prostate surgery, we chose to include an adapted version of the QPP questionnaire into the database.

The QPP questionnaire has a scientific basis and was originally developed after qualitative patient interviews [105]. The questionnaire is described as including four dimensions of patient-perceived quality of care: the caregivers' medical/technical competence, the identity-oriented approach toward the patients, the organization's physical/technical conditions and the organization's sociocultural approach. The two first dimensions are person-related and assess the perceived quality of competence of the health personnel involved and how patients rate the quality of information about treatment and adverse effects. The physical/technical dimension is concerned with whether up-to-date equipment is available, and the sociocultural approach dimension assesses whether the health care unit is focused on its patients or its staff. All items are answered on a four-point Likert scale with "not applicable" as a fifth option. A short-form version of the QPP has been developed [106].

The QPP differs from most other PREM questionnaires as it measures both patient-perceived quality and their subjective opinion of importance of the same aspects of quality of care [101]. In order to assess this, the same question is asked twice. First, the patients rate their perceived quality of care; second they rate the importance of the same matter. The Likert scale on perceived quality of care range from "totally agree" to "not agree at all." The scale for subjective importance goes from "very important" to "not important at all." The patients are first encouraged to rate the perceived quality of this information from "totally agree" to "not

agree at all" Afterwards, they are asked the same question, but now they are asked to rate how important it was to get information about examinations and treatment on a scale from "very important" to "not important at all." In this way, the QPP was designed to identify both how patients perceive the quality of care and how they rate the subjective importance of each issue. If there is a discrepancy between how they rate one aspect of perceived quality of received care and its subjective importance, the idea is that this could be used to identify areas for provider improvement.

The QPP has previously been validated and applied to other groups of patients in Norway [107], and items are routinely added to make the questionnaire more relevant to different settings. In order to adapt the short version of the QPP for RARP patients, items regarding specific adverse effects and help received to cope with these adverse effects were added. These questions were tested and found relevant by a group of peers, who were also involved in the process of formulating the items. The final version of the adapted QPP used in Paper 2 consisted of thirty items that were asked twice to assess both patient perceived quality and subjective importance.

Based on the results of Paper 2, only five items from the adapted QPP were retained for the study presented in Paper 3. These questions read as follows: "I received good information about adverse effects.", "I received good information about urinary adverse effects.", "I received good information about sexual adverse effects.", "I received help for urinary adverse effects." and "I received help for sexual adverse effects." These questions were answered on a 4-point Likert scale from "totally agree" (0) to "not agree at all" (3). "Not applicable" was also an option.

Assessments included in Papers 2, 3 and 4

Paper 2: To test the construct validity of the adapted short version of the QPP, we used data from 265 consenting patients who filled out the questionnaire as inpatients. Analysis was performed on thirty items concerning perceived quality of care.

Paper 3: To evaluate the association between patient-reported symptoms at baseline and follow-up and experience measures, we used a baseline EPIC-CP and an EPIC-CP with five additional items from the QPP at follow-up for 235 men.

Paper 4: To investigate predictors of histological upgrading at prostatectomy in men with low-grade cancer, we used information about age, PSA, PSA density, PI-RADS score, and T-stage on MRI from 130 men.

H: Statistics

Paper 1: No statistical analysis was performed. The paper presented descriptive information about the study population and adherence.

Paper 2: Patient characteristics were described as means, SD, and minimum and maximum values for continuous variables and as frequencies and percentages for categorical variables. The QPP items were described as frequencies and percentages, and to make comparison with previous studies on the QPP possible, means and SDs were also calculated. Questions marked "not applicable" were considered to be missing values. Factor analysis was performed to capture the structure of the adapted QPP. Since new items were added to the existing QPP, explorative factor analysis, rather than confirmatory factor analysis, was performed. The analyses were conducted using different statistical approaches. For the extraction of factors, three methods were employed: principal factors, principal-component factors, and the iterated principal factor method. Additionally, an analysis missing inputs was performed for the purposes of comparison with previous studies on the QPP. Internal consistency of the identified factors was assessed with Cronbach's α. The analyses were performed in SPSS v26 and Stata/SE v16.1

Paper 3: Patient characteristics were presented as means and minimum and maximum values for continuous variables and as frequencies and percentages for categorical variables. The total EPIC-CP scores, as well as the scores for the urinary incontinence domain and the sexual symptoms domain, were reported as means and standard deviations (SDs) stratified by the dichotomized (totally/largely vs. partially/do not agree at all) answers to the five selected items from the QPP. Dichotomization was necessary due to the small category size. Patients with missing and "not applicable" answers were excluded from the analysis. A logistic regression model (both unadjusted and adjusted for age and education) was estimated to

assess the association between total EPIC score and how men rated the quality of information about adverse effects.

Likewise, logistic regression models (unadjusted and adjusted for age and education) were estimated to assess the association between domain scores (urinary incontinence/sexual domains) and the patients' perceived quality of information about and help received for these specific problems. A linear regression analysis of the follow-up EPIC as an outcome and baseline EPIC as a score of how men rated the information and the interaction between them as independent variables was used to explore the differences between the men who rated the information as good and those who rated information as less good. Scatter plots were generated as illustrations. Next, differences between baseline and follow-up EPIC scores were calculated and dichotomized between worsening scores or improving scores. An χ^2-test was performed to investigate the association between how the information was rated and its symptoms. Four men with stable EPIC scores were exclude from this analysis. Statistical analyses were performed using an SPSS v27. The significance level was set at 5%.

Paper 4: Clinical characteristics were described by medians, minimum and maximum values, means, and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables. Logistic regression models (unadjusted and adjusted) were estimated to assess whether the preoperative factors were predictive of the outcome of a histological upgrade to GG 2–5 in the prostatectomy specimen. The adjusted model included age, PSA density, PI-RADS (dichotomized to 1–3 versus 4–5) and MRI stage (T1–2 versus T3a or T3b). Odds ratios with 95% confidence intervals were calculated. The association between PSA density and the probability of upgrading among patients with PI-RADS 1–3 and PI-RADS 4–5 on MRI was explored using a logistic regression model for PSA density, PI-RADS and the interaction between the two. All tests were two-sided, and results with p-values

< 0.05 were considered to be statistically significant. Statistical analyses were performed with SPSS v26.

I: Ethical considerations

All patients gave their informed consent to participate. Approval for all parts of the project was received from the Regional Committee for Medical Research Ethics, Health Region South-East (REF 2017/1257), Norway and the Data Protection Office for Research at Innlandet Hospital Trust. Furthermore, an additional application concerning Paper 4 was sent to the Regional Committee for Medical Research Ethics (REF2021/229048) in 2021. The study in Paper 4 was not a part of the original project description, so a new application was necessary.Due to the study's design, i.e., the fact that the studies assessed the quality of care for patients treated with RARP, the Regional Committee for Medical Research Ethics did not find it necessary for us to apply for further approval, either in 2017 or in 2021. The study was performed according to the rules of the Helsinki-declaration. Participation did not conflict with the participants' treatment and did not involve any health risks or deviations from good clinical practice.

J: Main findings

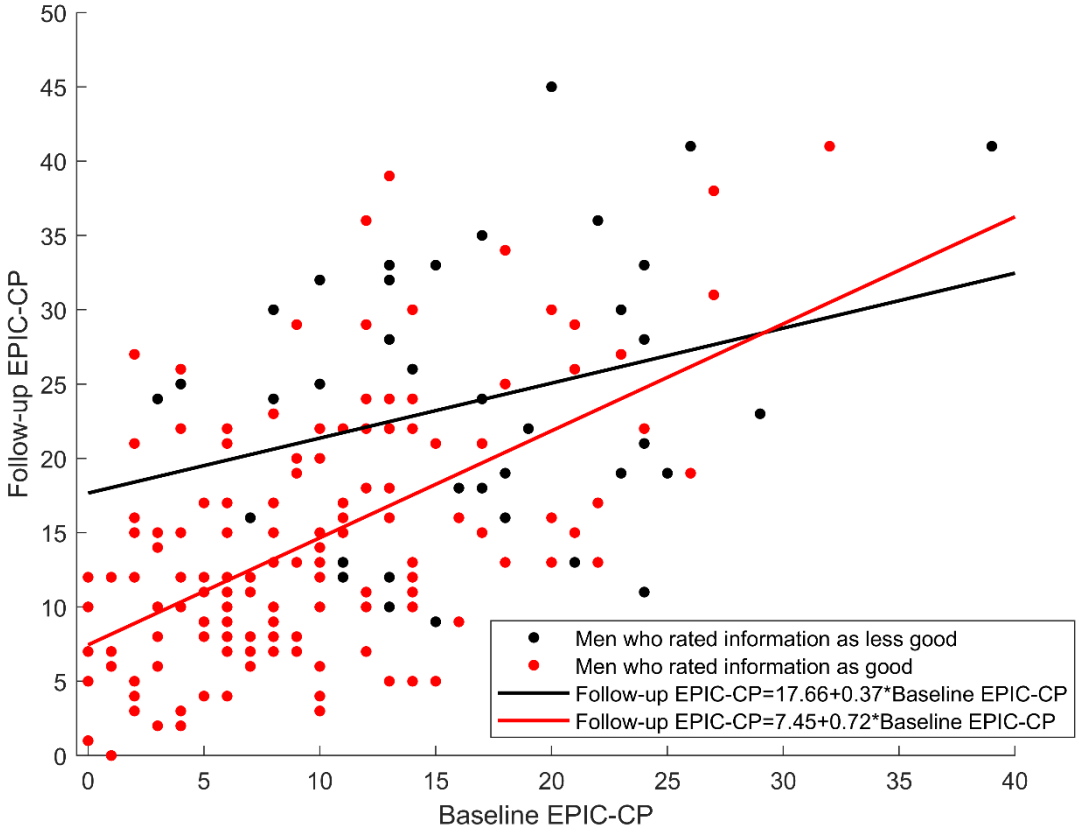
Paper 1 describes a database where data-entry is a natural part of the workflow. The structured forms were developed for both registration and documentation. The idea behind the database was shown to fulfill its purpose. Between August 1, 2017 and June 8, 2018, 182 (91%) of the 200 eligible patients gave their consent to participate. EPIC-CPs were completed by 176 patients (97%) at baseline and 165 (91%) after three months. Baseline QPPs were completed by 142 patients (78%). Adherence from the clinicians was good, and the functionality of the three structured forms was as intended.

In Paper 2, 361 eligible patients gave their consent to participate. Of these, 265 (73.4%) answered the adapted QPP. We found that the patients perceived the quality of care as generally good. The proportion of missing answers on each item was quite low, ranging from nine (3.4%) to twenty-six (9.8%). After starting to analyze results, we discovered that some patients, we don't know exactly how many, received an incorrect questionnaire. In some questionnaires there were a different set of responses for items concerning subjective importance. Specifically, instead of options ranging from "very high importance" to "little or no importance" the options ranged from "totally agree" to "not agree at all". As a result, factor analysis was performed on items covering perceived reality. Regarding the structure of the QPP, we were not able to reproduce the four theoretical dimensions. After factor analysis, seven factors explaining 64.9% of the variance were identified. When the missing answers were imputed, we found that two factors explained 48.6% of the variance. Despite using different methods for exploratory factor analysis, we could not find a pattern in the QPP and items from different dimensions were grouped together. Additionally, the distribution was skewed. From a clinical point of view, our conclusion was that the QPP in its present form

had limited value due to the skewed distribution of answers and a possible lack of differentiation.

In Paper 3, 235 (89%) of 265 men with available baseline data filled in the follow-up surveys in February 2021, at twenty to forty-two months after RARP. The majority, 182 (77%), rated the quality of information as good. We found that more symptoms measured with EPIC-CP at follow-up were associated with poorer perceived quality of pretreatment information about adverse effects and help with adverse effects. This association was also present when the results were adjusted for age and level of education. When looking at the quality ratings of the men who reported worsening EPIC scores from baseline to follow-up as compared to those who reported an improvement, we found that the proportion who reported sufficient and good information was almost identical in these two groups (78.3% and 79.2%). The association between patient-reported symptoms at baseline and follow-up stratified by patients who reported increased or decreased symptoms is illustrated in Figure 7. Although we assumed that worsening EPIC scores from baseline to follow-up was the results of adverse effects, our conclusion was that adverse effects could not explain our findings. Even though the majority rated the quality of information as good, there is room for improvement in communication and information distribution before an RARP.

Figure 7: Scatterplot showing the association between patient-reported symptoms at baseline and follow-up, stratified by patients who reported increased or decreased symptoms after RARP:

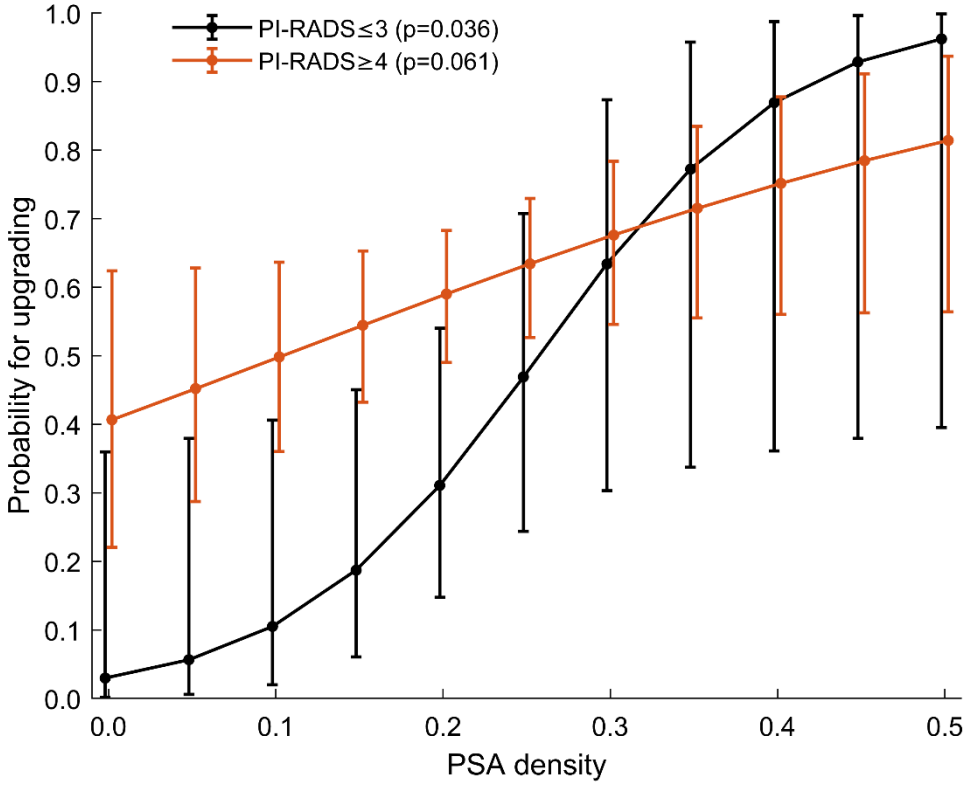


Black line—men who reported more symptoms at follow-up.
Red line—men who reported fewer symptoms at follow-up.

In Paper 4, upgrading from low-grade cancer at RARP was present in seventy-three (56%) of 130 men. PSA density was found to be the only significant predictor for upgrading. Despite being a predictor of upgrading, when stratified by the patient's PI-RADS score, we found that the probability of upgrading was high regardless of PSA density in men with PI-RADS scores 4 or 5 (see Figure 8). In contrast, for men with PI-RADS score ≤ 3 based on MRI analysis, the probability of upgrading was positively associated with PSA density. We concluded that findings based on MRI analysis can add valuable information for clinicians as men with a low

PSA density and no suspicious findings on an MRI have a low probability of having their cancer upgraded.

Figure 8: The association between PSA density and the probability of upgrading from biopsy at RARP as stratified by PI-RADS 1–3 and PI-RADS 4–5.



K: Discussion of main findings

Functionality of the database

The main advantage of the local database is how the clinical data are captured from the EMR. Transferal from the EMR to the database is automatic, and the system is simple. The simplicity of the structured forms is, however, both a strength and a weakness. With the present solution, it is not possible to create XLM-files with mandatory fields in the EMR, and the forms can be approved with missing data. However, the most up-to-date version of the forms are synchronized with and incorporated into the database, and if data is missing, the forms can be completed later on. Collecting information this way reduces the burden of registration and increases data quality, mainly because manual registration, which involves a risk for errors in every step, is avoided. Our way of collecting administrative, clinical and patient-reported data showed good adherence. The system is designed for this particular EMR, but the idea behind the system could easily be reproduced, adapted and further developed at other institutions with different EMRs.

Content of the database

Originally designed to transfer data without further entries to the national registry, the choice of the clinical parameters of the database reflected the requirements of this register. The most ideal procedure for seamless the transfer of clinical data would have been that having content in the structured forms identical to the national registry. However, local adaptions were made, and additional measurements regarded as important to quality assurance were included. An example of this is the size in millimeters of cancer in surgical margins. The content in quality databases for prostate cancer is debatable. Donabedian's model for the evaluation of quality of care includes structure indicators, process indicators and outcome indicators. The "Trifecta" that are commonly used for quality assurance after RARP, consist only of outcome measures. An international panel has suggested twelve quality indicators for prostate cancer

patients [109] that cover quality indicators from all parts of Donabedian's triade. Additionally, a proposed standard set of outcomes for men with localized prostate cancer has been published by an international group of patients, urologists, radiation oncologists and experts on registries [111]. Most of the suggestions in this set of standards are included in our local database but some are lacking. For instance, we don't register the number of positive diagnostic biopsies or greatest percentage involvement in biopsy cores. This might be reasonable as the process of performing biopsies has changed over the years. The number of positive cores is less informative when the currently recommended procedure, i.e., targeted biopsies, is performed. When registering of complications, the Clavian classification is generally preferred; however, we chose to use the system (NOTES) suggested by the MUSIC collaborative in Michigan for this. The reason for this choice was the simplicity of these registrations as we assume that, for instance, readmission is a reliable and objective measure of severe complications. For PROMs, the working group proposed using EPIC-26, but a PREM was neither suggested nor recommended. When the database was developed, we chose the shortest EPIC version (EPIC-CP) instead of EPIC-26 for patient-reported outcomes. This choice was made mainly because it is shorter and thus easier to summarize domain and total scores in EPIC-CP in contrast to EPIC-26 [127]. A short questionnaire reduces the burden for the patients; a lengthy questionnaire could cause fatigue bias [128]. In the latest version, we have switched to the EPIC-26. We made this change for two reasons: EPIC-26 is recommended by the International Consortium for Health Outcome Measurement (ICHOM) [111], and this version is already part of the national registry in Norway. When choosing EPIC-26, data could easily be delivered directly to the national registry. The drawback is that EPIC-26 is longer than EPIC-CP and thus more time-consuming to complete. For PREM, we chose the QPP as this questionnaire had previously been tested, validated, and applied on

other group of patients in Norway [105-107] and there was no consensus on which PREM to use for prostate cancer patients.

Structured documentation and quality

In this work, structured documentation in the EMR was the source used to capture administrative and clinical data. Data from structured forms are in many ways ideal for research purposes and quality assurance. Structured data can easily be analyzed with statistical software, and the main advantage is an increased capture rate thanks to computable data [129]. The literature indicates that a higher quality of care is provided with structured documentation. One example of this is the documentation of blood pressure in primary care, which was found to be more complete when doctors used structured documentation [130]. Similar findings are supported by others [131-133]. For surgeons, templates or proforma used to describe an operation instead of original text has been shown to be more effective and increase the quality of documentation [131, 132]. In a study of documentation in interventional radiology, documentation of selected parameters was more complete with structured forms [133]. A challenge for all registrations is missing data. A possible solution to securing complete follow-up data may be structured forms with mandatory fields becoming a natural part of the workflow. Another issue in quality assurance is the accuracy of the obtained data. Data entry with drop-down menus and boxes increases the accuracy as compared to other methods of data entry such as auto-filling with unstructured data and entry by paper [134, 135]. The structured forms in our local database are composed of drop-down menus and boxes, and we presume that this increased the accuracy of our registrations.

Structured documentation has weaknesses. One problem is clinician resistance to using the forms [136]. A solution to this problem is to make it mandatory to use the forms, as it was for this system. An alternative to capturing clinical data from the EMR without requiring manual entry is using information from unstructured documentation as text, which has been described

as natural language processing [137]. The American Association of Urology has developed a registry called AQUA where the extraction software captures information directly from text [138]. The software is applied to different EMRs so the burden of manual registration is reduced. The downside of the system is its complexity and cost. In order to address these problems, systems that use text phrases have been developed. They are less expensive and do not require natural language processing [139]. Another limitation with structured forms is that some information is lost. Free text can add valuable information, and a combination of structured and unstructured documentation is preferred. In conclusion, our experience was that the use of structured forms reduced the burden of registration and increased the capture rate of clinical data. We used a combination of structured and unstructured documentation.

Patient-reported experiences, QPP and quality of care

PREMs are important process measures of the patient journey and should be a part of clinical quality databases. Since there is no established PREM questionnaire for patients with prostate cancer, we included and tested the construct validity of the questionnaire Quality from the Patients' Perspective (QPP) in the register [105, 106].

The QPP was developed after qualitative patients interviews and validated in previous studies. Hence, it has a scientific basis. It describes four theoretical dimensions of patient-centered quality of care [105, 106]. One main argument for choosing this questionnaire was that it assesses both patient-perceived quality of quality of care and the subjective importance of the same aspect.

In our analysis, we could not reproduce the dimensions or pattern of the QPP. A possible reason for this is the former methods' limitations in validating the questionnaire. For instance, when assessing the dimensionality of a questionnaire, it is recommended that factor analysis be performed on all items simultaneously [140, 141]. This was not done in the original study

on the QPP [105]. Furthermore, earlier publications do not describe the statistical approach in detail or address how missing items were handled [105, 106]. It is also not clear if statisticians participated in the analysis [142].

Inadequate validation is a problem for many existing PREM questionnaires. A systematic review has evaluated eighty-eight identified PREMs with a revised version of the COSMIN checklist [108]. More than half of the questionnaires did not fulfill seven out of the ten criteria required for validity and reliability. This highlights the challenge of choosing a PREM questionnaire. The QPP was not included in this study. Another systematic review in which the QPP was one of the eleven identified questionnaires stated that all of them had undergone sufficient psychometric testing despite the fact that the quality of methods were variable [101].

In our study, the distribution of answers was skewed. The ceiling effect and skewness could be due to the properties of a questionnaire. A PREM should detect differences in experiences between individuals if there are any real differences. The ability to discriminate is important for all measurements [143]. Whether or not the QPP has this ability is unclear. If a highly skewed distribution was found in other studies using the QPP, is uncertain as they only report descriptive statistics (e.g., mean values) on single items, which provides limited information about the distribution [107] .

The adapted short version of QPP used in Paper 2 consists of thirty, two-part items, meaning the questionnaire is lengthy, which could explain why no more than 73.4 % (265/361) of the eligible men responded. The response rate was acceptable, but a higher response rate was predicted as the patients were encouraged to fill-in the questionnaire during their hospital stay. We also found that the responses on perceived quality of care and the subjective importance of the same item had quite similar distributions; however, these findings must be interpreted with caution since some patients received a questionnaire with a different set of

possible responses. The correlation between the distribution of the answers on items concerning perceived quality of care and subjective importance is line with other publications about the QPP [106, 107], which might not be surprising given that the QPP was developed after patient interviews aimed at identifying which aspects of care are most important from a patients' perspective. Due to this correlation, the number of items in the QPP could be reduced to shorten the questionnaire. Indeed, focusing only on the perceived quality of care would half the number of items. One would assume that how patients respond to the same item with respect to perceived quality and subjective importance is overlapping.

A goal with PREMs is to use the results for quality improvement. The incorporation of PREMs in routine practice is relatively new, and there is limited evidence on how results from PREMs are used for quality improvement [144]. In a randomized study in a primary-care setting, fifteen clinics who were given real-time feedback from patient experiences did not perform better than fifteen clinics randomized not to receive feedback [145]. The primary outcomes in this study were changed from baseline in nine items from the PREM questionnaire from the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) [145]. On the other hand, a review found an association between positive patient experiences and improved process of care, including better clinical outcomes, better efficiency and improved safety [146]. In a cross-sectional study of diabetic patients, adherence to prescribed treatment was better for patients who assigned higher ratings to the clinicians' communication skills [147]. In conclusion, some scientific evidence that results from PREM can be used to improve a focus on patient-centered care and secondarily improve other aspects of quality of care [148].

In this work we concluded that the QPP questionnaire in its present form was unsuitable for RARP patients. The skewed and uniform distribution of responses limits its clinical value for quality improvement. Having this said, our results do not preclude the possibility that the QPP

could be useful in other settings and for other groups of patients. The QPP was developed in Sweden, and since 2015, the questionnaire has since been a part of the Swedish National Quality Register of Gynecological Surgery. In a recent publication, the instrument was tested on gynecological patients and found suitable [142, 149]. Additionally, the questionnaire gives the patients the chance to evaluate improvable aspects of care, such as quality of information and being treated with respect by doctors and nurses.

As a result of our findings, the QPP is no longer in use at our institution. In order to evaluate the association between outcomes and experiences, we chose to retain five questions from the adapted QPP in the follow-up questionnaire in Paper 3.

Patient evaluation of quality and associations symptoms

In our study on the association between patient-reported symptoms and perceived quality of information about adverse effects and information to help to cope with adverse effects, we found that men who reported more symptoms at follow-up rated the quality of previously provided information lower. Although the majority rated the preoperative information as good, a substantial proportion of men in our cohort disagreed or partially disagreed. Information about coping with urinary and sexual adverse effects received the poorest ratings.

This highlights an important aspect of care: providing information that is sufficient and understood. Perceived quality of information is a structure measure and a vital PREM [91]. Our results are in keeping with findings in other studies, which identifies information from doctors as core area for improvement [150]. For patients undergoing RARP, sufficient and useful information is important as these men will live with potential adverse effects for years to come [151]. Our findings indicate a need to focus on communication to improve patient experiences. Programs for improving communication skills and how to practice shared-

decision making should be emphasized in the education and training of clinicians [152]. Such training programs have been shown to be valuable [153].

We found that experience measures were associated with patient-reported symptoms. The relationship between different patient-reported data has also been explored by other studies. A systematic review found that expectations were inconsistently associated with PROMs [154]. The majority of the included publications found that positive expectations were correlated with better outcomes, although some studies reported opposite the results. There is, however, limited research and knowledge in this field. A recent, large scale single-center study with more than 4,000 surgical patients evaluated the association between complications, incidents, patient-reported problems and overall experiences [155]. An incident was defined as an event or circumstance that could have resulted or did result in unnecessary harm to a patient. The fifteen-item Picker Patient Experience Questionnaire was used to detect patient problems and experiences, using a global rating of positive or negative experiences. Patients who reported positive experiences were older, and fewer of them had severe complications. In this study, complications and incidents were only associated with overall negative experiences if the patients reported other problems, such as lack of continuity or respect for patient preferences. The authors stated that increased attention to the discharge process and respect for patient preferences should be areas for improvement, especially if complications occur. In another study on orthopedic patients, rating of the doctors' communication skills and trust in their doctors were associated with better outcomes [148]. The examples above illustrate the complexity of patient-reported data and the associations between expectations, experiences and outcomes. Experience measures seem to be influenced by expectations, former experiences, and outcomes [91].

In our study, we presumed that increased symptoms from baseline to follow-up was a measure of adverse effects. Our results demonstrated an association between quality ratings of

information and symptom burden, but this relationship was not explained by adverse effects. We found that the share of men who reported fewer symptoms after treatment and rated the quality of information as good was almost identical to the share who reported more symptoms and rated the quality of information as good. This implies that not only outcomes, but symptoms influence experiences. Additionally, expectations could have an impact on the quality ratings. This again points to the importance of sufficient, easy-to-understand information and of taking the patient's current situation into consideration. For men newly diagnosed with prostate cancer, information must be provided early in the patient's journey. In this phase, they might not be responsive to information about adverse effects but rather focus on having their cancer treated. Additionally, the psychological aspect of being diagnosed with cancer might play a role on how information is perceived [156]. In our study, information about coping with urinary and sexual adverse effects received the poorest ratings and increased focus on this information is particularly warranted.

We found that a large share of men had fewer symptoms as compared to baseline as measured using the total EPIC-CP score after treatment. One possible explanation for this is that the total EPIC-CP score evaluates several symptoms, some of which are likely to be improved by surgery whereas others are not. Thus, for instance a likely surgical benefit for irritative and obstructive symptoms may lead to the improvement of sum scores even if adverse effects in terms of, for instance, leakage emerges. A problem presented on the item concerning a weak urinary stream or incomplete bladder emptying is that 19.1% reported that this represented a moderate or big problem at baseline and only 6.9 % at follow-up. This may emphasize the importance of providing individualized treatment. Men with lower urinary tract symptoms might experience fewer overall urinary symptoms after RARP. Our results also highlight the importance of comparing follow-up data to baseline measures.

Predictors of upgrading at radical prostatectomy

Predictors of histological upgrading from biopsy at radical prostatectomy are an important matter for urologists. The current tools for risk stratification have weaknesses. If we were able to identify men with a high probability of having a cancer with another prognosis, this would presumably improve individual advice about treatment options [73].

There are several earlier publications concerning predictors of upgrading, but studies incorporating MRI findings are relatively few. The reason for doing another study was to evaluate how findings on biparametric MRIs contribute. In our cohort 56% (73/130) experienced upgrading, and PSA density was the only significant predictor. This is in keeping with other previous research [74, 75, 157, 158]. A large-scale, population-based study showed that approximately 50% of men eligible for active surveillance had their cancer upgraded from a Gleason score 6 (grade group 1) and/or upstaged to a pT3 after radical prostatectomy [76]. High PSA, PSA density < 0.15 ng/mL/cm^3, clinical stage T2, biopsy core length above 4 mm and older age were identified as predictors of upgrading or upstaging [76]. The authors concluded that PSA density and the length of positive biopsy cores should be considered before active surveillance is recommended. Equal rates of upgrading and upstaging were found in another large-scale study on men eligible for active surveillance. Age, PSA and percentage of positive cores were associated with carrying either a higher grade or T3 cancer [77].

There is evidence that a PI-RADS score on an MRI predicts upgrading. In a single-center study on men with grade group 1 cancer and multiparametric MRI results, upgrading was found in 62.6% of patients. For men with PI-RADS 5 lesions, 70.5% had their cancer upgraded, and upgrading was found in 48.3% with PI-RADS 3 [159]. Other studies, also concerning upgrading or upstaging from low-grade cancer, have concluded that PI-RADS 4 or 5 were independent predictors of upgrading [160, 161]. A nomogram to predict upgrading

with incorporation of MRI findings has also been developed and has recently been reported to improve prediction [79].

In contrast to these studies, we didn't find PI-RADS scores to be a significant predictor of upgrading. One explanation may be differences in patient cohorts and study design. Studies from larger, academic hospitals are not necessarily representative of non-academic hospitals. In our study, we only included men with low-grade prostate cancer, whereas others have looked at patients in all grade groups. Another possible explanation is the limited sample size. However, given the strong association between PI-RADS score and grade group in a diagnostic setting, it is reasonable to expect that PI-RADS scores contribute to upgrading from low-grade cancer at prostatectomy.

When we stratified patients according to PI-RADS scores, we found that PSA density had clinical value as a predictor of upgrading for men with PI-RADS 3 or lower, but to a lesser degree for men with higher PI-RADS scores. This finding has clinical implications and to our knowledge, has not formerly been reported. Our conclusion is that PSA density is a strong predictor of upgrading during a radical prostatectomy for men with PI-RADS score 1–3 on bpMRIs. For men with PI-RADS scores of 4 or 5 on bpMRIs, the probability of upgrading is high regardless of PSA density.

Different potential predictors have been investigated by others. The expression of genetic biomarkers, such as miRNA, is associated with upgrading and can stratify which men are at risk of upgrading [162]. There is also evidence that p2PSA, an isoform of free-PSA, has a high specificity of prostate cancer. A mathematical model with three different biomarkers (PSA, free-PSA and p2PSA) called the Prostate Health Index has been developed and has been showed to outperform other predictors during a prostatectomy among patients of all grade groups [163]. Another option is measuring the stiffness of the tissue with ultrasound

shear-wave elastography. Ultrasound shear-wave elastography and PSA were found to be a more significant predictors for upgrading than PSA density and PI-RADS score [164].

In conclusion, there is evidence that information from an MRI can predict upgrading after prostatectomy. Our results suggest that PSA density is only of importance in men with a PI-RADS score of 1–3 after a bpMRI, but this needs to be confirmed in future studies.

L: Methodological considerations and limitations

Methodological considerations related to the database

Our code-driven system only enrolled patients with the code for RARP. Hence, incorrect coding is a possible limitation. Coding was not validated, but incorrect coding is presumed to be a minor problem. As the registry only enrolled patients undergoing RARP, this limits its value. For instance, are men on active surveillance or men who receive other treatment modalities were excluded. The upside of the system is a high capture rate. Additionally, similar code-driven systems could also be applied to other procedures and groups of patients.

The cloud-based system for the electronic collection of consent and patient-reported data for our database developed by Innlandet Hospital Trust was hacked in 2020. In general, cybersecurity is a challenge in healthcare. A leak of sensitive patient information from EMRs is a common problem. It has been reported that more than 90% of electronic health records are exposed to cyberattacks [165]. As a result of the hacking episode, we had to change our routine, and patient-reported data is now collected via another similar system developed by Oslo University Hospital. The security issue we experienced is a possible limitation of electronic and cloud-based systems, both in general and for the system described in this thesis.

Methodological considerations related to the PREM questionnaire

The choice of PREM is questionable. Despite the scientific basis of the QPP, we have found that earlier publications that used the QPP have weaknesses and that former validation [105, 106] is in many ways insufficient. The handling of missing items has not been described in detail by the developers, and earlier publications using the QPP have approached this problem differently. Another concern is the way factor analysis has been performed. In the article in which the QPP was originally described, items were analyzed separately for each dimension [105]. When assessing dimensionality, factor analysis should be performed on all items

simultaneously. The questionnaire is lengthy, and questionnaires with fewer items are preferable so as to reduce the burden for the patients.

In our study, the number of missing items was relatively few. The number of non-applicable responses, considered to be missing in Paper 2, could be due to the timing of when the patients were presented with the questionnaire. The QPP was completed early in the patient's journey: after surgery, but before discharge. Questions concerning help with adverse effects are not relevant at this time but are more appropriate to ask some months or maybe years after treatment. If the patients were asked to fill out the QPP later in the patient's journey, the number of non-applicable responses would probably be reduced.

A major limitation was that some patients, we don't know exactly how many, received the QPP with different response options. As the same question was asked twice, first to evaluate the perceived quality and then to evaluate the subjective importance of the same matter, the response options differed between the two. Perceived quality was rated from "totally agree" to "not agree at all", while questions concerning the subjective importance of the same matter were rated from "very important" to "not important at all." In some of the electronic questionnaires, there was an error as the response option was the same for both aspects. Hence, the patients were asked to rate subjective importance from "totally agree" to "not agree at all". Consequently, factor analysis was performed only on items regarding the perceived quality of care. Whether this error altered our results is uncertain as the distribution of the answers were quite similar for both those who were presented with the correct questionnaire and those who responded to the wrong one.

As a result of our findings in Paper 2, the QPP is no longer in use. A weakness of Paper 3 is that we used selected items from the adapted QPP rather than a fully validated questionnaire.

Other methodological considerations

Study design

The single-center design of this thesis reduces the generalizability of the findings and conclusions. Furthermore, an observational design, in contrast to the gold standard of a randomized control trial, may also be seen as a study weakness. Observational studies can only describe associations and generate hypotheses, as opposed to experimental studies that can prove causality. However, the observational design, which also applies to similar, registry-based studies, describes real world data and is valuable for quality assurance. Furthermore, the research questions of this thesis cannot be answered by an experimental study.

Sample size/selection bias

The small sample size of Paper 2 represents a possible limitation [166]. The sample size is also a limitation of Paper 4, especially given the limited number of men with a PI-RADS 3 after an MRI. For this reason, the number of potential factors in the regression analysis were reduced to secure power. Consequently, there is need for studies with larger cohorts to reproduce and confirm the results of this study.

Selection bias is a weakness of Paper 4 as these men were selected for surgery. Additionally, the study included men with low-grade cancer not only low-risk cancer. Some of the men in the study's cohort were not eligible for active surveillance. Risk stratification and treatment recommendations are made on the basis of PSA and tumor stage in addition to histological grade. In our study, some men with stage T3 cancer and a PSA above recommendations for active surveillance were included, and these men should be advised to receive radical treatment regardless of the risk of upgrading.

In Papers 2 and 3, selection bias may have occurred, as we have no information from those who did not answer the questionnaires.

Recall bias/Measurement bias

In Paper 3, recall bias is a possible limitation as patients are asked to rate information they were given several months previously and thus may not have an exact memory of the information they were given. Therefore, there is a chance that experiences and outcomes could have influenced their responses.

We cannot exclude the possibility that measurement bias could have contributed to the results of Paper 4. A general problem with a prostate MRI is the inter-reader variability. In observational studies like this, the interpretation of MRIs could impact the results. The MRIs were not externally reevaluated. PI-RADS scores were assigned by different uroradiologists and staged by a single, experienced radiologist at Innlandet Hospital Trust. Furthermore, the grade group was consecutively established by different pathologists, in the same way as MRI findings. This was, however, a consequence of the study's design.

Only a few potential predictors of upgrading were investigated in our study. This was done to secure sufficient power. The PI-RADS scores were dichotomized due to the small number of patients, especially those with PI-RADS score ≤ 3. An additional reason was the true clinical dichotomization between these groups, namely: PI-RADS ≤ 3 do harbor significant clinical cancer to a much smaller degree than PI-RADS 4 or 5.

In our analysis tumor stage was defined by MRI instead of digital rectal exploration. This is somewhat controversial as clinical staging is the standard procedure according to current guidelines [21]. A stage one MRI was not found to be a significant predictor of upgrading. In the study cohort 21.5% (28/130) had a stage T3a or T3b after receiving an MRI. This might have impacted on our results.

Statistical approach

The statistical approach in Paper 2 is questionable. Our results showed highly skewed distributions of answers, which make statistical evaluation problematic. Moreover, when

evaluating established questionnaires, confirmatory factor analysis is often the method of choice [166]. However, as new items were added and there was no hypothesis to be tested, exploratory analysis was applied. Several models for exploratory factor analysis were estimated, but none of them could reproduce the dimensionality of the QPP, which strengthens our study. Additionally, missing items were computed in order to make comparisons with earlier publications about the QPP possible.

M: Future directions

Data from registries used for benchmarking

In order to provide high quality health registries, data must be accurate and complete. Clinical registries aim to measure performance, make comparison on performance between institutions possible (benchmarking) and secure quality. Hence, they should contain process and outcome measures. Process measures are more direct measures of quality while differences in outcomes could be due to widely varying factors, such as differences in patient cohorts, differences in measurements, random variation and real differences in quality of care [95]. For benchmarking, confounders in patient cohorts such as age, comorbidity and socio-economic status might influence outcomes and should be adjusted for.

For patients undergoing RARP in particular, a collection of patient-reported data is crucial. Due to the natural course of localized/locally advanced disease with generally good prognosis, there are minimal differences in five-year survival rates between institutions. Hence, the focus should be on other measurements of quality of care. PROMs concerning functional results such as urinary incontinence and sexual symptoms are more relevant as quality measurements. However, variation in functional outcomes could be due to patient factors. Consequently, comparison between follow-up data and baseline data is paramount for the evaluation of urinary incontinence and sexual symptoms after an RARP.

Additionally, patient-reported data, both at baseline and follow-up appointments, must be as complete as possible. If not, selection bias can occur as the responders might not be a representative for the populations under study [128].

The national registry in Norway has low capture rates of PROM, and a possible solution to this problem is to collect PROM in the local registries. Central administration takes time, and since these men are enrolled in a structured diagnostic pathway and begin treatment after a

short period, local collection of PROM might be more effective and secure more complete data. On the other hand, there is research suggesting that patients may downplay adverse-effects when patient-reported data are collected by the treating institution as compared with a third party [167]. On an institutional level, feed-back on performance increases interest for registries [168]. With increased motivation for local registries, the potential high capture rate in such registries can provide more reliable data for benchmarking in multi-institutional and population-based registries, if data from different registries are merged.

As outcome measures are influenced by different factors, process measures, like adherence to guidelines and the number of high-risk patients that receive treatment, are in general more suitable for benchmarking.

The local database

Over the years and in the future, our local database has been and will be continuously evolving. Since the first version, the content and functionality of the structured forms have changed. For patients undergoing RARP, we now use one single form instead of three. The same form follows the patient during their whole treatment journey, beginning with their surgery. The drop-down menus have been altered; they are now constructed with numbers, not text, to make data computable and facilitate transmission to statistical software. This illustrates the fact that clinical databases are dynamic. In the future, improved technical solutions will increase the potential to capture and utilize data already contained in the EMRs.

Transferal of data from the local registry to the national registry is not currently established, but the infrastructure needed for doing so is. Hopefully, data will automatically be transferred in the forthcoming years.

PREMS in clinical registries:

In order to provide patient-centered care, collection of PREMs is mandatory. PREMs are process measurements, and these tools instruments will almost certainly have a greater place in the evaluation of quality of care for years to come. Experience measures can identify areas for improvement, such as communication between urologists and patients. A consequence of the results of Paper 3 is an increased focus on information about coping with adverse effects, which received poorest ratings. In the future, PREM questionnaires should be a part of clinical registries for patients with prostate cancer. We no longer use the QPP but will continue to search for another PREM questionnaire for patients who are undergoing RARP.

Predictors of upgrading

Regarding predictors of upgrading and the contribution to this from MRI findings, artificial intelligence might improve the diagnostic precision and interpretation of MRIs. Machine learning, radiomics and deep learning could be valuable in reducing inter-reader variability and improving sensitivity. A recently published review on bpMRIs found comparable results on cancer detection rates between AI-techniques and radiologists in the majority of the papers [169]. None of the studies that directly compared the performance of AI with radiologists concluded that either approach was superior. However, AI-techniques have value for untrained radiologists who need to improve their performance and generate reports with sufficient quality. This again can be used to rule out patients with the highest probability of having significant cancers. Still regarded as experimental today, these techniques are likely to be further developed in the coming years [170]. Another field that is rapidly evolving is genetic tests. When these tests become routine in clinical practice, individual prognoses can be made to provide help in decision-making.

N: Conclusions/Clinical implications

Paper 1: The functionality of the database was good as were adherence and completeness. Designed for quality assurance and research, the intended purposes were fulfilled. We will continue to further develop our local database and the use of structured documentation for quality improvement.

Paper 2: We tested the construct validity of the QPP but couldn't reproduce the theoretical dimensions and structure of the questionnaire. Consequently, we stopped using the QPP. For patients with prostate cancer, other PREMs must be considered.

Paper 3: More patient-reported symptoms at follow-up were significantly associated with lower quality ratings of preoperative information about adverse effects and coping with them. The degree of adverse effects could not explain this finding. We further found that the majority rated the quality of information as good, but a substantial share of men did not. The clinical impact of our results is that they highlight the importance of sufficient and understandable information. For urologists, training in communication skills could be valuable.

Paper 4: In men with low-grade cancer and bpMRIs, we found PSA density to be the only significant predictor of upgrading during a prostatectomy. When stratified according to PI-RADS scores, men with PI-RADS scores of 4 or 5 from a bpMRI were found to have a high probability of upgrading regardless of PSA density. For men with PI-RADS score of 1–3, the probability of upgrading was associated with PSA density. This finding has clinical implications as men with low-grade cancer, low PSA density and no suspicious tumors displayed on an MRI should be informed about the low probability of having significant cancer and advised to consider active surveillance. Men with low-grade cancer, high PSA-

density and PI-RADS 1–3 and men with low-grade cancer and PI-RADS 4–5 should be advised to treat their cancer.

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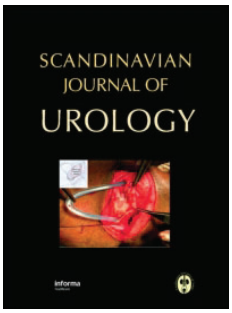

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TECLA—an innovative technical approach for prostate cancer registries

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Construct Validity of the Questionnaire Quality From the Patients Perspective Adapted for Surgical Prostate Cancer Patients

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Abstract

Patient-reported experience measures (PREMs) are important to capture the patients' voice. No such measure is routinely used for evaluation after robotic-assisted radical prostatectomy for prostate cancer. The aim of this study was to adapt the short version of the PREM questionnaire quality from the patients' perspective (QPP), and assess the construct validity of this version. Quality from the patients' perspective assesses 4 dimensions of quality of care. Involving discussion with user representatives, the QPP short version was adapted by adding 7 context-specific questions based on items from the Expanded Prostate Cancer Index Composite for Clinical Practice. This short version was answered on smartphone or tablet by 265 patients. We used exploratory factor analysis to assess dimensionality. For comparison with previous publications of the QPP, the analysis was repeated after mean imputation of missing values. The factor analysis identified 7 factors among the 30 analyzed items included in the analysis, explaining 64.9% of the variance. After imputation of missing, 2 factors explained 48.6% of the variance. None of these analysis captured the 4 dimensions of the QPP.

Keywords

PREMs, prostate cancer, perceived quality of care, construct validity

Background

Prostate cancer is the most common cancer among men, and in Norway, the lifetime prevalence is about 15% (1). The natural history of prostate cancer varies from low-risk disease with good prognosis without treatment, to high-risk disease with rapid progression (2). Hence, treatment is individualized, and management varies according to patient characteristics (age, comorbidity), patient preferences, and disease factors (tumor stage and histologic grade). To avoid overtreatment and adverse effects, patients with low-risk disease are normally observed. Patients with intermediate and high-risk disease and a life expectancy over 10 years are offered treatment with curative intention. According to current guidelines, standard curative or radical treatment is either external radiation therapy or surgery, currently most often in the form of robotic-assisted radical prostatectomy (RARP) (3). Both these treatment may reduce quality of life (4). After surgery, the most common long-term adverse effects are urinary incontinence and erectile dysfunction.

Patient-reported outcome measures (PROMs) are essential to evaluate treatment outcomes and to assure good quality of care. Several questionnaires have been developed for this

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purpose. Until recently, no standard PROM questionnaire has been used for patients with prostate cancer, but the International Consortium for Health Outcomes recommends Expanded Prostate Cancer Index Composite (EPIC) (5). However, to capture the patients' voice and meet the criteria for quality of care defined by the World Health Organization (WHO) (6), it is necessary to combine PROMs with patient-reported experience measures (PREMs). Despite current recommendations (7), systematic collection of PROMs and PREMs is often missing in clinical registries (8) and PREMs are not routine for the evaluation of prostate cancer treatment (9). For surgical prostate cancer patients, a PROM measure would be urinary adverse effects, while a PREM measure is how they experience the information about adverse effects and involvement in decisions about their treatment.

Choosing a proper PREM questionnaire to evaluate prostate cancer care is a challenge, as there are few available instruments and no gold standard (10,11). The Swedish questionnaire quality from the patients' perspective (QPP) is a PREM questionnaire that has been tested and validated in other settings and patient groups (12,13). A short version has been translated to Norwegian. The aim of this study was to adapt the QPP short version specifically for patients with prostate cancer treated with RARP and to assess the construct validity of this adapted version.

Methods

Setting and Routines

The Urological Department at Innlandet Hospital Trust treats about 200 patients with RARP each year. Patients referred for surgery receive oral and written information about the procedure and possible adverse effects, and if they consent, they are enrolled in a local quality database (14). The database includes clinical data and PROMs assessed by the Expanded Prostate Index Composite for Clinical Practice (EPIC-CP) (15). In August 2017, an adapted short version of the QPP was included in the quality database. Prior to discharge, the patients completed the QPP using a tablet or smartphone. They were encouraged to complete the questionnaire without assistance. Eligible patients (treated with RARP, Norwegian speaking, providing informed consent) were consecutively recruited to participate in this study from August 2017 to June 2019.

Questionnaire

The original QPP is based on qualitative patients' interviews, aiming to identify the aspects of care that matter the most to the them (12). A short form was later developed (13).

The QPP is intended to assess 4 dimensions of quality: (a) the caregivers' medical/technical competence; (b) identity-oriented approach toward the patients; (c) the organization's physical-technical conditions; and (d) sociocultural approach (12). The caregivers' medical/technical competence and identity-oriented approach are person-related dimensions. The former includes the perceived quality of the involved health personnel's competence and the latter assesses whether the patients feel sufficiently informed about planned treatment and adverse effects. The physical–technical dimension concerns whether up-to-date equipment is available, and the sociocultural approach dimension assesses whether the health care unit is constructed for and oriented to the patients rather than for and to its staff.

The QPP differs from other PREM questionnaires in that it assesses the subjective importance of all items (10). The patients are presented multiple statements on the quality of various aspects of care, for which they are asked to respond on a Likert scale from "do not agree at all" (1) to "totally agree" (4). For each item, they are asked to report its perceived importance on a scale from "little or no importance" (1) to "very high importance" (4). "Not applicable" options are also available.

To adapt the QPP short version to prostate cancer patients, 7 context-specific questions based on items from EPIC-CP were added. Expanded Prostate Cancer Index Composite for Clinical Practice assesses urinary and sexual adverse effects (15). The context-specific questions assess the patients perceived quality and importance of the information given about these adverse effects and the help they received to better cope with them. To ensure that the additional items were understandable and relevant, the adapted version was tested on 5 user representatives previously treated with RARP. The process involved discussion with each representative and presentation of QPP for the whole group. The final QPP version included 30 items assessing perceived quality and the same 30 questions about the subjective importance of these items.

Statistical Analysis

Patient characteristics were described as means, SD, minimum and maximum values for continuous variables, and as frequencies and percentages for categorical variables. The QPP items were described by frequencies and percentages, yet to allow comparison with other studies, also means and SDs were calculated. Responses "not applicable" were considered as structurally missing values. The pattern of other missing values was explored by creating a dummy variable for missing values for each item, and running a multiple logistic regression model with a dummy variable as outcome and patient characteristics as explanatory variables (16). When any of the considered characteristics were significantly associated the dummy variable, missing data were assumed not to be missing conditionally at random, which is usually considered a prerequisite for analyzing data sets with missing values.

As new items were added to the short version of QPP, the absence of a hypothesis precluded a confirmatory factor analysis for assessing the dimensionality of the questionnaire. Exploratory factor analysis was therefore applied for the adapted QPP. For extraction of factors, 3 methods were

employed, principal factors, principal-component factors, and iterated principal factor method. The number of factors was assessed by applying the Kaiser's criterion of eigenvalues equal to or larger than 1.0, followed by parallel analysis. The extracted factors were further rotated by *varimax* and *promax* methods for easier interpretation.

A matrix of Spearman's correlations was employed as input for exploratory factor analysis, an appropriate approach for skewed ordinal data. Additionally, and entirely for comparison to other studies, the same analysis was performed with missing values, also those structurally missing, replaced by the mean values of existing items.

Internal consistency of the identified factors was assessed with Cronbach's α, where the values close to 1 indicate good internal consistency of the scale (17). As Cronbach's α is sensitive to deviations from normality, omega coefficient was presented as well (18). The analyses were performed in SPSS v26 and Stata/SE v16.1.

Results

From August 2017 to June 2019, 361 patients gave their consent to inclusion in the quality assurance database and to participate in the present study. Of these, 265 (73.4%) completed the adapted short version of QPP. Their mean age was 66 years (38-79, SD = 6.5 years). Twenty-six percent had 9 years of obligatory school, 38% had high school education, and 33% an academic degree.

Overall, the patients rated the quality of care as good (Table 1). The proportion of missing items ranged from 3.4% (9/265) to 9.8% (26/265), the lowest percentage for "I receive examination and treatment within an acceptable waiting time," and the highest for "I receive help for sexual adverse effects." The proportion of items considered "not applicable" ranged from none to 34.7% (92/265). The item most often considered as "not applicable" was "I receive help for sexual adverse effects." The reported subjective importance for the items showed similar pattern (Table 1).

After starting to include patients, we discovered that some patients received a questionnaire with incorrect answering options for subjective importance. Instead of presenting the options ranging from "little or no importance" to "very high importance," they were presented with options ranging from "do not agree at all" to "totally agree." Consequently, the main analyses were based on data for the 30 items covering perceived quality.

For several items, the patterns of missing values showed that these values were not likely to be "missing conditionally at random" (data not presented), making most imputation methods questionable. Spearman's correlations for the 30 items assessing perceived quality showed no clear pattern (Table 2). The exploratory factor analysis with the principal factor extraction method resulted in 19 factors. As most of these factors contained only weakly loading items, this solution was not explored further.

The principal component factor method identified 7 factors (Table 3), with the same structure obtained by applying *promax* and *varimax* rotation, that explained 64.9% of variation of the scale. Factor-1, consisting of 7 items, explained 35.5% of the variance (Cronbach's α 0.86 and ω 0.90). Factor-2 consisted of 9 items but explained only 9.2% of the variance. The remaining factors contained 2 to 3 items and explained little of the variance.

Iterated principal factor method with *varimax* rotation resulted in 4 factors with loadings higher than when *promax* rotation was used. The 4 factors explained 52.2% of the variance (Table 3) and showed quite good internal consistency, but the structure was difficult to interpret. Factor 1 was largest and consisted of 17 items, while factor 3 and factor 4 only contained 2 items.

In all analyses, the Kaiser's criterion agreed well with the results of parallel analysis. The exploratory factor analysis on items with missing values imputed by the average of the existing items for each patient, gave a completely different factor structure. The model identified only 2 factors, with factor 1 consisting of 19 items contributing with 49.0% of explained variance, while factor 2 included the remaining 11 items but explained only 11.1% of the variance (results not shown).

Discussion

We adapted a short version of the QPP questionnaire for patients treated with RARP and assessed its construct validity. However, we did not identify the 4 previously described dimensions of the QPP questionnaire.

Our main analysis (principal component factor method) identified 7 factors. Factor-1 included items from 3 dimensions: the caregivers' medical/technical competence, their identity-oriented approach toward the patients, and the organization's physical–technical conditions. Factor 2 included items from the identity-oriented dimension and items that addresses the caregivers' medical/technical competence. In addition, items from the identity-oriented dimension were presented in 4 different factors, and closely related items in the same dimension loaded on different factors. Items in the sociocultural approach dimension loaded on 3 different factors, and although all items addressing the caregivers' medical/technical competence loaded on the same factor (factor 1), this factor also included items from 2 other dimensions. Thus, we found no clear pattern among items and were not able to differentiate 1 dimension from another in our data set. Analysis with iterated principal factor method identified 4 factors, but no clear structure was found.

To enable comparisons with former studies on the QPP, we performed an exploratory factor analysis after imputing missing values with the mean of existing items on each patient. This resulted in a 2-factor solution, which was very different from those found in our main analyses. This might indicate that mean imputation affects the correlation structure in a considerable way. Furthermore, the structure of the

Table 1. Distributions of Scores for Each Item.[a]

	Mean (SD)	Missing, n (%)	Score 0, n (%)	Score 1, n (%)	Score 2, n (%)	Score 3, n (%)	Score 4, n (%)
A: Items addressing perceived reality							
I receive good information about examination and treatment	3.8 (0.5)	10 (3.8)	1 (0.4)	0	2 (0.8)	37 (14.0)	215 (81.1)
I receive good information about results of examination and treatment	3.7 (0.5)	14 (5.3)	0	2 (0.8)	3 (1.1)	55 (20.8)	191 (77.2)
I receive good information about how to take care of myself	3.6 (0.7)	14 (5.3)	3 (1.1)	0	6 (2.3)	69 (26.0)	173 (65.3)
I receive good information about which doctors who are responsible	3.6 (0.7)	15 (5.7)	1 (0.4)	6 (2.3)	15 (5.7)	44 (16.6)	184 (69.4)
I receive good information about which nurses who are responsible	3.4 (0.9)	14 (5.3)	2 (0.8)	11 (4.2)	28 (10.6)	54 (20.4)	156 (58.9)
I receive good information about my illness	3.6 (0.6)	16 (6.0)	0	1 (0.4)	9 (3.4)	68 (25.7)	171 (64.5)
I receive good information about adverse effects	3.6 (0.7)	14 (5.3)	3 (1.1)	2 (0.8)	11 (4.2)	74 (27.4)	161 (60.8)
I receive good information about urinary adverse effects	3.5 (0.9)	18 (6.8)	8 (3.0)	2 (0.8)	8 (3.0)	59 (22.3)	170 (64.2)
I receive good information about bowel adverse effects	3.0 (1.2)	14 (5.3)	16 (6.0)	12 (4.5)	47 (17.7)	70 (26.4)	106 (40.0)
I receive good information about sexual adverse effects	3.4 (1.0)	16 (6.0)	12 (4.5)	0	17 (6.4)	64 (24.2)	156 (58.9)
I receive the best possible medical care	3.9 (0.3)	13 (4.9)	0	0	1 (0.4)	21 (7.9)	230 (86.8)
I receive help for pain	3.9 (0.5)	11 (4.2)	2 (0.8)	0	2 (0.8)	26 (9.8)	224 (84.5)
I receive examination and treatment within an acceptable waiting time	3.7 (0.6)	9 (3.4)	1 (0.4)	2 (0.8)	11 (4.2)	47 (17.7)	195 (73.6)
I receive help for urinary adverse effects	2.9 (1.6)	17 (6.4)	51 (19.2)	2 (0.8)	8 (3.0)	42 (15.8)	145 (54.7)
I receive help for bowel adverse effects	2.5 (1.6)	16 (6.0)	66 (24.9)	4 (1.5)	29 (10.9)	51 (19.2)	99 (37.4)
I receive help for sexual adverse effects	1.9 (1.7)	26 (9.8)	92 (34.7)	6 (2.3)	30 (11.3)	49 (18.5)	62 (23.4)
I have access to necessary equipment	3.6 (1.0)	14 (5.3)	14 (5.3)	1 (0.4)	4 (1.5)	35 (13.2)	197 (74.3)
I have access to necessary urinary pads	3.6 (1.0)	12 (4.5)	17 (6.4)	0	4 (1.5)	17 (6.4)	215 (81.1)
Doctors seem to understand how I experience my situation	3.8 (0.5)	14 (5.3)	0	1 (0.4)	6 (2.3)	45 (17.0)	199 (75.1)
Doctors are respectful toward me	3.9 (0.3)	12 (4.5)	0	0	1 (0.4)	18 (6.8)	234 (88.3)
Doctors show empathy for me	3.8 (0.4)	13 (4.9)	0	0	2 (0.8)	44 (16.6)	206 (77.7)
Nurses seem to understand how I experience my situation	3.9 (0.3)	12 (4.5)	0	0	1 (0.4)	17 (6.4)	235 (88.7)
Nurses are respectful toward me	3.9 (0.3)	11 (4.2)	1 (0.4)	0	0	12 (4.5)	241 (90.1)
Nurses show empathy for me	3.9 (0.3)	17 (6.4)	0	0	0	17 (6.4)	231 (87.2)
I have good opportunity to participate in the decisions regarding my treatment	3.5 (0.9)	10 (3.8)	10 (3.8)	0	18 (6.8)	59 (22.3)	168 (63.4)
My relatives and friends are treated with respect	3.0 (1.7)	21 (7.9)	55 (20.9)	0	4 (1.5)	15 (5.7)	170 (64.2)
There is a pleasant and secure atmosphere on the ward	3.8 (0.6)	12 (4.5)	3 (1.1)	1 (0.4)	1 (0.4)	27 (10.2)	221 (83.4)
My care is determined by my own request rather than staff procedures	3.4 (1.0)	16 (6.0)	8 (3.0)	6 (2.3)	21 (7.9)	63 (23.8)	151 (57.0)
I have the opportunity to talk the doctors undisturbed	2.0 (1.9)	14 (5.3)	106 (40.0)	9 (3.4)	9 (3.4)	22 (8.3)	105 (39.6)
I have the opportunity to talk to the nurses undisturbed	2.0 (1.9)	19 (7.2)	111 (41.9)	4 (1.5)	8 (3.0)	19 (7.2)	104 (39.2)
B: Items addressing subjective importance							
I receive good information about examination and treatment	3.8 (0.4)	30 (11.3)	0	0	2 (0.8)	38 (14.3)	195 (73.6)
I receive good information about results of examination and treatment	3.8 (0.4)	28 (10.6)	0	0	1 (0.4)	49 (18.5)	187 (70.6)
I receive good information about how to take care of myself	3.6 (0.7)	32 (12.1)	3 (1.1)	0	4 (1.5)	65 (24.5)	161 (60.8)

(continued)

Table 1. (continued)

	Mean (SD)	Missing, n (%)	Score 0, n (%)	Score 1, n (%)	Score 2, n (%)	Score 3, n (%)	Score 4, n (%)
I receive good information about which doctors who are responsible	3.6 (0.7)	27 (10.2)	2 (0.8)	4 (1.5)	11 (4.2)	50 (18.9)	171 (64.5)
I receive good information about which nurses who are responsible	3.4 (0.9)	27 (10.2)	3 (1.1)	7 (2.6)	22 (8.3)	64 (24.2)	142 (53.6)
I receive good information about my illness	3.7 (0.6)	30 (11.3)	0	2 (0.8)	4 (1.5)	64 (24.2)	165 (62.3)
I receive good information about adverse effects	3.6 (0.8)	31 (11.7)	4 (1.5)	0	13 (4.9)	52 (19.6)	165 (62.3)
I receive good information about urinary adverse effects	3.5 (0.9)	31 (11.7)	9 (3.4)	2 (0.8)	10 (3.8)	46 (17.4)	167 (63.0)
I receive good information about bowel adverse effects	3.1 (1.2)	36 (13.6)	16 (6.0)	4 (1.5)	29 (10.9)	66 (24.9)	114 (43.0)
I receive good information about sexual adverse effects	3.3 (1.1)	38 (14.3)	15 (5.7)	3 (1.1)	16 (6.0)	57 (21.5)	136 (51.3)
I receive the best possible medical care	3.9 (0.3)	38 (14.3)	0	0	1 (0.4)	19 (7.2)	207 (78.1)
I receive help for pain	3.8 (0.6)	33 (12.5)	2 (0.8)	0	5 (1.9)	25 (9.4)	200 (75.5)
I receive examination and treatment within an acceptable waiting time	3.8 (0.6)	32 (12.1)	1 (0.4)	1 (0.4)	8 (3.0)	33 (12.5)	190 (71.7)
I receive help for urinary adverse effects	2.9 (1.6)	37 (14.0)	47 (17.7)	1 (0.4)	6 (2.3)	40 (15.1)	134 (50.6)
I receive help for bowel adverse effects	2.5 (1.7)	38 (14.3)	61 (23.0)	2 (0.8)	15 (5.7)	47 (17.7)	102 (38.5)
I receive help for sexual adverse effects	2.1 (1.7)	48 (18.1)	77 (29.1)	3 (1.1)	22 (8.3)	56 (21.1)	59 (22.3)
I have access to necessary equipment	3.6 (1.0)	37 (14.0)	14 (5.3)	0	1 (0.4)	41 (15.5)	172 (64.5)
I have access to necessary urinary pads	3.6 (1.0)	42 (15.8)	15 (5.7)	0	2 (0.8)	18 (6.8)	188 (70.9)
Doctors seem to understand how I experience my situation	3.8 (0.5)	33 (12.5)	0	1 (0.4)	3 (1.1)	35 (13.2)	193 (72.8)
Doctors are respectful toward me	3.9 (0.2)	37 (14.0)	0	0	0	13 (4.9)	215 (81.1)
Doctors show empathy for me	3.9 (0.4)	33 (12.5)	0	0	1 (0.4)	32 (12.1)	199 (75.1)
Nurses seem to understand how I experience my situation	3.9 (0.3)	33 (12.5)	0	0	1 (0.4)	15 (5.7)	216 (81.5)
Nurses are respectful toward me	3.9 (0.2)	34 (12.8)	0	0	0	13 (4.9)	218 (82.3)
Nurses show empathy for me	3.9 (0.3)	34 (12.8)	0	0	0	17 (6.4)	214 (80.8)
I have good opportunity to participate in the decisions regarding my treatment	3.5 (0.9)	37 (14.0)	8 (3.0)	0	11 (4.2)	50 (18.9)	159 (60.0)
My relatives and friends are treated with respect	3.1 (1.6)	42 (15.8)	46 (17.4)	0	4 (1.5)	17 (6.4)	156 (58.9)
There is a pleasant and secure atmosphere on the ward	3.9 (0.5)	41 (15.5)	2 (0.8)	1 (0.4)	0	21 (7.9)	200 (75.5)
My care is determined by my own request rather than staff procedures	3.4 (0.9)	40 (15.1)	8 (3.0)	2 (0.8)	18 (6.8)	54 (20.4)	143 (54.0)
I have the opportunity to talk the doctors undisturbed	2.0 (1.9)	42 (15.8)	93 (35.1)	8 (3.0)	10 (3.8)	23 (8.6)	89 (33.6)
I have the opportunity to talk to the nurses undisturbed	2.0 (1.9)	41 (15.5)	98 (37.0)	6 (2.3)	11 (4.2)	19 (7.2)	90 (34.0)

[a]The table includes 30 items covering perceived reality followed by the same 30 items for subjective importance. Data are presented as mean scores, SD, frequencies and percentages. The 4-point Likert scale for items addressing perceived reality ranges from 1: Do not agree to 4: Totally agree. The scale for items addressing subjective importance ranges from 1: Little or no importance to 4: Very high importance. For all items 0 = not applicable.

Table 2. Spearman's Correlations among 30 Items Representing Perceived Reality Calculated on All Available Pairs of Items.

	3	5	7	9	11	13	15	17	19	21	23	25	27	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59
1. I receive good information about examination and treatment	0.6	0.3	0.3	0.3	0.4	0.4	0.4	0.3	0.5	0.4	0.3	0.3	0.5	0.3	0.3	0.4	0.3	0.5	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.4	0.2
3. I receive good information about results of examination and treatment		0.4	0.4	0.4	0.6	0.4	0.5	0.4	0.4	0.3	0.3	0.3	0.5	0.4	0.4	0.4	0.3	0.4	0.3	0.4	0.3	0.3	0.3	0.4	0.4	0.2	0.4	0.4	0.2
5. I receive good information about how to take care of myself			0.3	0.4	0.4	0.4	0.4	0.3	0.4	0.2	0.2	0.2	0.4	0.3	0.3	0.3	0.2	0.3	0.2	0.3	0.3	0.3	0.3	0.4	0.3	0.4	0.2	0.3	0.2
7. I receive good information about which doctors who are responsible				0.5	0.3	0.3	0.4	0.3	0.2	0.3	0.1	0.2	0.3	0.2	0.3	0.3	0.3	0.4	0.3	0.5	0.3	0.3	0.3	0.4	0.4	0.3	0.3	0.4	0.3
9. I receive good information about which nurses who are responsible					0.4	0.2	0.3	0.4	0.2	0.3	0.2	0.2	0.4	0.4	0.3	0.3	0.2	0.3	0.3	0.3	0.4	0.3	0.3	0.4	0.3	0.2	0.3	0.3	0.3
11. I receive good information about my illness						0.5	0.5	0.4	0.5	0.3	0.3	0.3	0.4	0.4	0.5	0.4	0.2	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.3
13. I receive good information about adverse effects							0.5	0.3	0.5	0.3	0.2	0.3	0.4	0.4	0.4	0.3	0.1	0.3	0.3	0.3	0.2	0.3	0.3	0.4	0.3	0.3	0.3	0.3	0.3
15. I receive good information about urinary adverse effects								0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.2	0.3	0.3
17. I receive good information about bowel adverse effects									0.3	0.2	0.2	0.3	0.4	0.6	0.4	0.3	0.1	0.3	0.1	0.3	0.2	0.1	0.1	0.4	0.1	0.2	0.2	0.2	0.3
19. I receive good information about sexual adverse effects										0.3	0.2	0.2	0.4	0.4	0.5	0.4	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.1
21. I receive the best possible medical care											0.5	0.3	0.2	0.2	0.1	0.3	0.4	0.4	0.4	0.4	0.5	0.5	0.6	0.3	0.5	0.4	0.3	0.2	0.1
23. I receive help for pain												0.3	0.4	0.3	0.2	0.3	0.4	0.2	0.2	0.2	0.4	0.3	0.4	0.2	0.4	0.4	0.3	0.3	0.2
25. I receive examination and treatment within an acceptable waiting time													0.3	0.3	0.2	0.3	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.2	0.3	0.3	0.1	0.0
27. I receive help for urinary adverse effects														0.6	0.4	0.4	0.3	0.4	0.3	0.3	0.3	0.2	0.3	0.4	0.2	0.2	0.2	0.3	0.2
29. I receive help for bowel adverse effects															0.6	0.3	0.2	0.4	0.2	0.3	0.3	0.2	0.2	0.3	0.1	0.2	0.3	0.3	0.2
31. I receive help for sexual adverse effects																0.4	0.2	0.3	0.2	0.3	0.1	0.2	0.1	0.3	0.1	0.2	0.4	0.4	0.3
33. I have access to necessary equipment																	0.5	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.3	0.3	0.4	0.3
35. I have access to necessary urinary pads																		0.3	0.5	0.4	0.5	0.5	0.4	0.2	0.5	0.4	0.2	0.2	0.1
37. Doctors seem to understand how I experience my situation																			0.6	0.6	0.5	0.4	0.5	0.5	0.4	0.4	0.4	0.4	0.4
39. Doctors are respectful toward me																				0.6	0.5	0.6	0.5	0.3	0.5	0.4	0.3	0.3	0.1
41. Doctors show empathy for me																					0.4	0.4	0.5	0.5	0.5	0.3	0.4	0.3	0.2
43. Nurses seem to understand how I experience my situation																						0.7	0.7	0.3	0.5	0.4	0.3	0.4	0.2
45. Nurses are respectful toward me																							0.7	0.4	0.6	0.5	0.3	0.4	0.3
47. Nurses show empathy for me																								0.4	0.6	0.4	0.4	0.4	0.3
49. I have good opportunity to participate in the decisions regarding my treatment																									0.3	0.4	0.5	0.3	0.4
51. My relatives and friends are treated with respect																										0.6	0.3	0.4	0.3
53. There is a pleasant and secure atmosphere on the ward																											0.4	0.3	0.1
55. My care is determined by my own request rather than staff procedures																												0.3	0.4
57. I have the opportunity to talk the doctors undisturbed																													0.7
59. I have the opportunity to talk to the nurses undisturbed																													

Table 3. Results of Exploratory Factor Analyses.[a]

	Principal-component factors method, *varimax* rotation							Iterated principal factor method, *varimax* rotation			
	F1	F2	F3	F4	F5	F6	F7	F1	F2	F3	F4
Proportion of variance explained	35.5	9.2	5.3	4.0	3.8	3.7	3.4	35.0	8.7	5.1	3.5
Cronbach's α	0.86	0.86	0.73	0.76	0.85	0.60	0.62	0.90	0.87	0.85	0.74
Omega	0.90	0.90	0.79	0.70	0.61	0.74	0.68	0.90	0.88	0.62	0.67
1. I receive good information about examination and treatment	0.33	**0.52**	0.20	0.39	0.01	−0.02	0.13	**0.50**	0.38	0.06	0.23
3. I receive good information about results of examination and treatment	0.19	**0.60**	0.22	0.21	0.08	0.03	0.36	**0.62**	0.28	0.16	0.13
5. I receive good information about how to take care of myself	0.15	**0.53**	0.13	0.00	0.09	0.14	0.35	**0.52**	0.23	0.16	0.05
7. I receive good information about which doctors who are responsible	0.18	0.26	0.02	0.26	0.15	0.18	**0.67**	**0.34**	0.31	0.26	0.22
9. I receive good information about which nurses who are responsible	0.18	0.12	0.45	0.09	0.17	0.05	**0.62**	**0.43**	0.19	0.24	0.21
11. I receive good information about my illness	0.14	**0.68**	0.23	0.07	0.12	0.05	0.20	**0.66**	0.22	0.17	0.03
13. I receive good information about adverse effects	0.08	**0.70**	0.07	0.13	0.06	0.32	0.01	**0.58**	0.21	0.11	0.08
15. I receive good information about urinary adverse effects	0.18	**0.65**	0.17	−0.03	0.13	0.08	0.22	**0.60**	0.25	0.18	−0.03
17. I receive good information about bowel adverse effects	−0.01	0.23	**0.64**	−0.03	0.13	0.22	0.31	**0.58**	−0.02	0.18	0.19
19. I receive good information about sexual adverse effects	0.18	**0.70**	0.22	0.19	−0.01	0.09	−0.28	**0.58**	0.23	−0.03	0.08
21. I receive the best possible medical care	**0.69**	0.22	0.11	0.03	−0.11	0.19	0.10	0.26	**0.65**	−0.03	0.06
23. I receive help for pain	**0.61**	0.18	0.36	−0.30	−0.03	0.20	−0.03	0.33	**0.44**	0.01	−0.03
25. I receive examination and treatment within an acceptable waiting time	0.24	0.30	0.25	−0.06	−0.33	**0.37**	0.25	**0.42**	0.27	−0.09	0.08
27. I receive help for urinary adverse effects	0.19	0.40	**0.63**	0.24	0.01	−0.10	0.12	**0.61**	0.14	0.03	0.26
29. I receive help for bowel adverse effects	0.08	0.27	**0.80**	0.14	0.07	0.15	0.01	**0.65**	0.01	0.05	0.31
31. I receive help for sexual adverse effects	−0.05	**0.49**	0.48	0.10	0.26	0.27	−0.09	**0.63**	−0.02	0.20	0.18
33. I have access to necessary equipment	0.38	**0.52**	0.13	0.01	0.21	0.07	0.13	**0.47**	0.39	0.21	0.02
35. I have access to necessary urinary pads	**0.68**	0.16	0.11	0.15	−0.02	−0.03	0.05	0.18	**0.59**	0.00	0.13
37. Doctors seem to understand how I experience my situation	0.33	0.15	0.28	**0.59**	0.24	0.25	0.09	0.29	0.35	0.23	**0.62**
39. Doctors are respectful toward me	0.56	0.14	0.08	**0.62**	−0.03	0.04	0.08	0.15	**0.60**	−0.02	0.48
41. Doctors show empathy for me	0.28	0.22	0.07	**0.63**	0.02	0.35	0.24	0.28	0.41	0.11	**0.53**
43. Nurses seem to understand how I experience my situation	**0.76**	0.01	0.14	0.23	0.17	0.06	0.11	0.10	**0.70**	0.16	0.24
45. Nurses are respectful toward me	**0.74**	0.14	−0.07	0.29	0.25	0.12	0.03	0.07	**0.76**	0.22	0.22
47. Nurses show empathy for me	**0.75**	0.16	0.04	0.25	0.20	0.13	0.05	0.15	**0.75**	0.18	0.21
49. I have good opportunity to participate in the decisions regarding my treatment	0.14	0.26	0.21	0.32	0.21	**0.51**	0.22	**0.41**	0.25	0.26	0.37
51. My relatives and friends are treated with respect	**0.69**	0.25	−0.19	0.08	0.14	0.23	0.30	0.16	**0.76**	0.21	0.03
53. There is a pleasant and secure atmosphere on the ward	0.51	0.18	0.00	−0.03	0.00	**0.58**	0.15	0.25	**0.53**	0.09	0.13
55. My care is determined by my own request rather than staff procedures	0.18	0.12	0.20	0.26	0.20	**0.68**	0.02	**0.30**	0.27	0.21	0.33
57. I have the opportunity to talk the doctors undisturbed	0.27	0.27	0.10	0.09	**0.75**	0.04	0.22	0.27	0.27	**0.67**	0.12
59. I have the opportunity to talk to the nurses undisturbed	0.09	0.15	0.15	0.03	**0.87**	0.18	0.10	0.20	0.07	**0.89**	0.13

[a] Factor loadings in bold face indicate factor for each item.

2-factor solution did not coincide with those reported in other patient groups (12,13,19).

Adding new items may explain that our results are inconsistent with the original QPP dimensions. We believe, however, that this discrepancy relates to different statistical approach. We have chosen to follow recommendations stating that the first step in assessing the dimensionality of a questionnaire is to explore the correlation matrix among items and to perform factor analysis on all items simultaneously as it is important to test if items in 1 dimension do not load on others (20,21). In other studies on the QPP, the lack of correlation matrix among the items limits the insight into the structure of the questionnaire and without factor analysis performed on all items simultaneously (12), it is not possible to assess cross-loadings, which might have revealed a different structure. Furthermore, Cronbach's α, as used in former QPP publications is not sufficient to assess dimensionality (12,13). Cronbach's α cannot be regarded as a measure of unidimensionality (22) but rather assumes that items constitute a single dimension and measure its internal consistency.

The distribution of answers on the items assessing perceived quality of care was highly skewed. A highly skewed distribution and a ceiling effect seem both to be a general, problematic characteristic of most existing PREM instruments (11). Whether this is the case for QPP when applied in other settings is not clear. Many previous studies have reported descriptive statistics for single items as means and SD only (19), which does not give an adequate picture of the data distribution. Moreover, we observed a high proportion of missing items and items considered not applicable, which implies difficulties when assessing construct validity. The management of missing values and the background for imputation methods are scarcely described in other studies of QPP (12,19).

From a clinical point of view, our results indicate that the patients were generally satisfied with their care. However, we intended to find a PREM questionnaire for surgical prostate cancer patients that provides relevant feedback and identifies areas in need of improvement, and the modified QPP cannot be recommended for routine use in its present form. Its clinical value is restricted by the ceiling effect, and we will thus continue our pursuit for a clinically useful PREM questionnaire for RARP patients. We will consider a questionnaire with fewer items to reduce the burden for the patients and improve the response rate.

A limitation of this study is that some patients received a questionnaire with incorrect response options for their perceived importance of the different items, which limited the analysis to data for perceived quality of care.

Conclusions

We were not able to identify the previously described dimensions of the QPP in our cohort of surgical prostate cancer patients. In its present form, QPP has limited clinical value to assess how patients with prostate cancer experience their care after RARP.

Authors' Note

The dataset used and analyzed during this study are available from the corresponding author on request. All patients gave their consent to participate. The study was approved by the Regional Ethics Committee in South East Norway (REF 2017/1257).

Declaration of Conflicting Interests

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III

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Article

Experience Measures after Radical Prostatectomy: A Register-Based Study Evaluating the Association between Patient-Reported Symptoms and Quality of Information

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Abstract: Patient-reported data are important for quality assurance and improvement. Our main aim was to investigate the association between patient-reported symptoms among patients undergoing radical prostatectomy and their perceived quality of information before treatment. In this single-centre study, 235 men treated with robotic-assisted radical prostatectomy (RARP) between August 2017 and June 2019, responded to a follow-up questionnaire 20–42 months after surgery. A logistic regression analysis was performed to assess the association between patient-reported symptoms, measured with Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP), and the perceived quality of information. Adverse effects were defined as a higher EPIC score at follow-up than at baseline. The majority (77%) rated the general information as good. Higher EPIC-CP at follow-up was significantly associated with lower perceived quality of information, also after adjustment for age and level of education (bivariate model OR 1.12, 95% CI 1.07; 1.16, $p < 0.001$ and multiple model OR 1.12 95% CI 1.08; 1.17, $p < 0.001$). The share who rated information as good was almost identical among those who reported more symptoms after treatment and those who reported less symptoms (78.3% and 79.2%). Consequently, adverse effects could not explain the results. Our findings suggest a need for improvement of preoperative communication.

Keywords: experience measures; robotic-assisted radical prostatectomy; PROMs

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1. Introduction

According to the World Health Organization, quality health services should be effective, safe, person-centred, timely, equitable, integrated and efficient [1]. Person-centred health care means that individual preferences should be taken into account [2], and implies that assessing user experience is important to secure and improve the quality of care. Patient-reported data capture the patients' voices, provide information for quality assurance and improvement, and include Patient-Reported Outcome Measures (PROMs), Patient-Reported Experience Measures (PREMs) and patient satisfaction. Examples of PROMs are measures of adverse treatment effects and health-related quality of life (HRQoL). PREMs are defined as person-centred measures evaluating different aspects of interactions with the health care system, such as information and communication [3]. Although the distinction between patient experience and patient satisfaction may sometimes be difficult to capture,

PREMs differ from measures of satisfaction [3,4]. PREMs aim to be process indicators that can identify differences in quality of care, for instance, differences in the quality of communication about adverse effects. Satisfaction measures, on the other hand, are subjective and closely related to the patient's expectation and former experiences [3,4].

Prostate cancer is one the most common cancers among men, thus a large number may suffer from adverse effects of their cancer disease and its treatment [5]. Men with localized (non-metastatic) disease have two established, potentially curative treatment options: radiotherapy and surgery [6,7]. Radiotherapy and surgery are equally effective but have different adverse effects [8]. In high-income countries, surgery for prostate cancer is often performed as robotic-assisted radical prostatectomy (RARP). Whereas bowel problems and urinary urgency are the most frequent side-effects after radiotherapy, the most common long-term consequences after RARP are urinary incontinence and erectile dysfunction [9]. All of these adverse effects may affect quality of life [7].

When assessing the quality of prostate cancer treatment, the International Consortium for Health Outcomes Measurement recommends that patient-reported adverse effects should be collected with the 26-item Expanded Prostate Cancer Index Composite (EPIC-26) [10,11]. EPIC is available in several different but compatible versions, the shortest of which is the 16-item Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) [12]. In contrast, there is no similar established questionnaire for PREMs for patients with prostate cancer. Ideally, PREMs should be independent of expectations or outcome [13]. Research suggests that the severity of adverse effects is associated with the grade of satisfaction and regret after radical prostatectomy [14,15], but whether this also applies to experienced quality of information before treatment is scarcely elaborated.

We have previously tested an adapted version of the PREM questionnaire Quality from the Patients Perspective (QPP) for patients with prostate cancer, which included items concerning patient-perceived quality of information and help to cope with adverse effects [16]. These items were used in the present study with the aim of investigating if the perceived quality of the preoperative information given about RARP and the help received were affected by symptoms after treatment and quality of life. Our primary hypothesis was that men who reported more and severe symptoms on the EPIC-CP rated the quality of the information about adverse effects before treatment as poorer than those who reported better EPIC-CP scores. Our secondary hypothesis was that worse scores on the EPIC-CP sub-domains for urinary incontinence and sexual adverse effects are specifically associated with poorer perceived quality of the information and help given about the related problems. Finally, assuming that the difference between EPIC scores at follow-up and baseline is a measure for adverse effects, we aimed to explore if adverse effects were associated with how patients rated quality of information.

2. Methods

2.1. Study Design

The study was a single-centre study based on a local database, developed for quality assurance and research.

2.2. The Database

The TECLA database has previously been described in detail [15]. In addition to clinical and descriptive data such as age and level of education, it includes PROMs (EPIC-CP) and PREMs at baseline and follow-up.

2.3. Population

Between August 2017 and June 2019, 361 patients underwent RARP, all of whom were included in the local quality database. Eligible patients for the present study were fluent in Norwegian, had provided informed consent, and had baseline data available, leaving 265 men. Of these, 235 (89%) had filled in a follow-up questionnaire in February 2021, 20 to 42 months after surgery.

2.4. Pre-Operative Information about Adverse Effects and Follow-Up

Once diagnosed, men eligible for radical treatment are discussed in a multidisciplinary meeting consisting of urologists, oncologists and radiologists. Afterwards, they have a pre-treatment consultation with a urologist with experience of RARP and are then informed about treatment options and adverse effects. The information is routinely given both orally and in writing, and the patients are encouraged to use web-based decision aids. If they wish, they are also offered an appointment with a radiation oncologist and/or a peer. During their journey from the pre-treatment consultation to postoperative follow-up, the patients are free to contact a coordinating nurse if they feel insufficiently informed. Patients who report bothersome urinary or sexual problems are offered an appointment with a urotherapist for help with symptom management.

2.5. Assessments

The EPIC-CP contains 16 items, of which 15 cover symptoms from five different domains: urinary incontinence, urinary irritation/obstruction, bowel symptoms, sexual symptoms and vitality/hormonal symptoms. Each domain includes three items scored on a Likert-scale, ranging from 0–4. These item scores are summarized into domain scores ranging from 0–12. The total EPIC-CP score thus ranges from 0 to 60. Higher scores mean more symptoms.

We have earlier tested an adapted version of the questionnaire Quality from the Patients Perspective (QPP) for collecting PREM, but we could not reproduce QPP's previously described dimensions [16]. As a result, we no longer routinely use the questionnaire but in this present study, we have included five selected QPP items about communication and coping with adverse effects.

The five retained QPP PREM items cover perceived quality of the information given about adverse effects and the help received to cope with these effects. The items read as follows: "I received good information about adverse effects", "I received good information about urinary adverse effects", "I received good information about sexual adverse effects", "I received help for urinary adverse effects" and "I received help for sexual adverse effects". These questions were answered on a 4-point Likert scale from "totally agree" (0) to "do not agree at all" (3). "Not applicable" was also an option. For the analyses, the answers were dichotomized into 0–1 (totally agree and largely agree) versus 2–3 (partly agree and do not agree at all).

2.6. Statistical Analysis

Patient characteristics were described as means and minimum and maximum values for continuous variables, and frequencies and percentages for categorical variables. The total EPIC-CP scores, as well as the scores for the urinary incontinence domain (Urinary Incontinence Symptom Score—UISS) and the sexual symptoms domain (Sexual Symptom Score—SSS), were reported as means and standard deviations (SDs) stratified by the dichotomised (totally/largely vs. partially/do not agree at all) answers on the five PREM items. Dichotomization was necessary due to the small category size. Patients with missing answers and "not applicable" were excluded from the analysis.

To assess the association between EPIC-CP total score and perceived overall quality of the information about adverse effects, a logistic regression analysis was performed. Logistic regression analysis was also performed to assess the associations between EPIC domain scores (urinary incontinence scores and sexual symptom scores) and patients' perceived quality of information about, and help received for these specific problems. All regression models were adjusted for age and education. We assumed that any association between perceived quality of information and EPIC was represented by an association between perceived quality of information and actual adverse effects (increasing symptoms from baseline to follow-up) or by an association between perceived quality of information and persisting symptoms from baseline. Linear regression analysis with follow-up EPIC score as outcome and baseline EPIC score, how men rated information and interaction between

the two as independent variables was performed to assess the differences between those who answered totally/largely agree and those who answered partially/do not agree at all, regarding the association between baseline and follow-up EPIC score. A significant interaction would imply that the interaction between baseline and follow-up EPIC is significantly different between those who answered totally/largely agree and those who answered partially/do not agree at all. Scatter plots were generated for illustrations (Figure S1, Supplementary). Next, differences between baseline and follow-up EPIC scores were calculated and dichotomized to worsening scores or improved scores. χ^2-test was applied to assess the association between how the information was rated and symptoms. Four men with stable EPIC scores were exclude from this analysis.

Statistical analyses were performed with SPSS v27. Significance level was set at 5%.

3. Results

Mean age of the study population was 66 years (37–79). In total, 27% had 9 years of obligatory school, 39% had a high school education, and 34% an academic education.

The mean total EPIC-CP was 10.8 (SD 7.8) at baseline and 16.5 (SD 9.6) at follow-up. The mean UISS was 1.0 (SD 1.6) at baseline and 2.7 (SD 2.8) at follow-up. The mean SSS was 3.5 (SD 2.9) at baseline and 7.7 (SD 3.4) at follow-up.

Of the 235 responders, 182 (77%) totally or largely agreed that they had received good information about adverse effects in general, 178 (76%) totally or largely agreed that they had received good information about urinary incontinence symptoms and 167 (71%) totally or largely agreed that they had received help with such symptoms. Although a majority gave a correspondingly positive answer when rating information on sexual symptoms and help with these adverse effects, fewer men totally or largely agreed on these items: 156 (66%) and 128 (54%) (Table 1).

Table 1. Descriptive statistics with distributions of answers of perceived quality of information and help to cope with adverse effects at follow-up.

	Totally Agree (0) or Largely Agree (1)	Partially Agree (2) and Do Not Agree at All (3)	Missing or Not Applicable
	N (%)	N (%)	N (%)
I received good information about adverse effects	182 (77)	50 (21)	3 (1.3)
I received good information about urinary adverse effects	178 (76)	52 (22)	5 (2.1)
I received good information about sexual adverse effects	156 (66)	69 (29)	10 (4.3)
I received help for urinary adverse effects	167 (71)	43 (18)	25 (11)
I received help for sexual adverse effects	128 (54)	75 (32)	32 (14)

The mean total EPIC-CP score at follow-up was 16.5 (SD 9.6). For men that answered that they totally or largely agree on the item "I received good information about adverse effects", the mean EPIC-CP score was 14.3 (SD 8.3), while men that answered that they partially agree or do not agree at all had a mean EPIC-CP score of 24.3 (SD 10.2). The same pattern was found for symptom scores for the urinary incontinence domain and the sexual symptoms domain (Table 2).

Table 2. Descriptive statistics of EPIC-CP total score, urinary incontinence symptom score (UISS) and sexual symptom score (SSS) stratified on PREM questions.

Outcome	Totally Agree (0) and Largely Agree (1)	Partially Agree (2) and Do Not Agree at All (3)
	I Received Good Information about Adverse Effects	
EPIC-CP (N = 216)		
N	171	45
Mean (SD)	14.3 (8.3)	24.3 (10.2)
	I received good information about urinary adverse effects	
UISS (N = 229)		
N	178	51
Mean (SD)	2.2 (2.3)	4.1 (3.0)
	I received help for urinary adverse effects	
UISS (N = 224)		
N	156	68
Mean (SD)	2.1 (2.3)	3.4 (3.0)
	I received good information about sexual adverse effects	
SSS (N = 203)		
N	163	40
Mean (SD)	7.6 (3.3)	9.1 (3.2)
	I received help for sexual adverse effects	
SSS (N = 196)		
N	125	71
Mean (SD)	7.1 (3.3)	9.0 (2.7)

EPIC-CP = Expanded Prostate Index Composite for Clinical Practice, UISS = Urinary Incontinence Symptom Score, SSS = Sexual Symptom Score.

In bivariate logistic regression analysis, how men rated the quality of the information they had received about adverse effects was significantly associated with the total EPIC-CP score; this association remained statistically significant after adjusting for age and level of education (Table 3). Significant associations were also found for the perceived quality of information about urinary adverse effects, sexual adverse effects, help to cope with adverse effects and the EPIC-CP scores on the corresponding domains (Table 3).

Table 3. Results of logistic regression analysis with dichotomized PREM items as outcome.

	Unadjusted Models		Adjusted Model	
	OR (95% CI)	***p*-Value**	**OR (95% CI)**	***p*-Value**
I Received Good Information about Adverse Effects (N = 208)				
EPIC-CP at follow-up	1.12 (1.07; 1.16)	<0.001	1.12 (1.08; 1.17)	<0.001
Age			0.96 (0.91; 1.01)	0.144
Level of education				
Obligatory—ref.			1	
High school			0.95 (0.35; 2.57)	0.921
Academic			1.12 (0.47; 2.70)	0.723
I received good information about urinary adverse effects (N = 220)				
UISS	1.27 (1.13; 1.43)	<0.001	1.27 (1.13; 1.43)	<0.001
Age			1.00 (0.95; 1.05)	0.949
Level of education				
Obligatory—ref.			1	
High school			0.68 (0.28; 1.66)	0.393
Academic degree			0.90 (0.42; 1.92)	0.787

Table 3. *Cont.*

	Unadjusted Models		Adjusted Model	
	OR (95% CI)	***p*-Value**	**OR (95% CI)**	***p*-Value**
I received help for urinary adverse effects (N = 217)				
UISS	1.20 (1.08; 1.34)	<0.001	1.20 (1.08; 1.35)	0.001
Age			0.99 (0.95; 1.04)	0.766
Level of education				
Obligatory—ref.			1	
High school			0.92 (0.41; 2.04)	0.835
Academic			1.20 (0.60; 2.39)	0.607
I received good information about sexual adverse effects (N = 195)				
SSS	1.16 (1.03; 1.30)	0.018	1.19 (1.05; 1.34)	0.007
Age			0.98 (0.92; 1.04)	0.473
Level of education				
Obligatory—ref.			1	
High school			0.39 (0.14; 1.07)	0.068
Academic			0.76 (0.34; 1.72)	0.510
I received help for sexual adverse effects (N = 189)				
SSS	1.23 (1.11; 1.36)	<0.001	1.27 (1.13; 1.43)	<0.001
Age			0.99 (0.94; 1.05)	0.837
Level of education				
Obligatory—ref.			1	
High school			0.28 (0.11; 0.67)	0.005
Academic			0.72 (0.35; 1.51)	0.385

More patient-reported symptoms at baseline were associated with more symptoms at follow-up (Figure S1, supplementary). This association was not statistically significant between those who rated the information as good and those who rated the information as less good (non-significant interaction terms). Of 177 men with all baseline and follow-up data available, 48 reported lower EPIC scores at follow-up compared to baseline, and 129 reported higher EPIC scores at follow-up compared to baseline. There were no differences in how information was rated between men with increase and decrease in symptoms from baseline to follow-up. (Table 4). Among those who reported less symptoms, 79.2% answered that they totally or largely agree on the item "I received good information about adverse effects", while this was found among 78.3% for men who reported more symptoms ($p = 0.900$ for χ^2-test).

Table 4. Descriptive statistics on the item "I received good information about adverse effects" stratified on men who reported less and more symptoms after treatment (defined as the difference between EPIC score at follow-up and baseline).

I Received Good Information about Adverse Effects	Totally Agree (0) and Largely Agree (1)	Partially Agree (2) and Do Not Agree at All (3)	
Total, N (%)	139 (78.5)	38 (21.5)	177
Men with less symptoms, N (%)	38 (79.2)	10 (20.8)	48
Men with more symptoms, N (%)	101 (78.3)	28 (21.7)	129

4. Discussion

In this register-based study including RARP patients, we found that although the majority reported having received good information and help with adverse effects, a substantial proportion disagreed or only partly agreed with such statements. These patients also reported more symptoms on follow-up, and the association between higher symptom score and quality ratings was significant and independent of age and level of education.

Higher baseline EPIC scores were associated with higher EPIC scores at follow-up. This association did not differ statistically between those who rated the information as good and those who rated the information as less good.

The association between patient-reported symptoms and perceived quality of information, as demonstrated in this study, has to our knowledge not been reported for radical prostatectomy patients. Our primary hypothesis was confirmed, but our results were not explained by adverse effects as the share of men who reported less symptoms after treatment and rated the quality of information as good was identical to the share who reported more symptoms and rated the quality of information as good.

Our results are not in line with previous studies addressing patient-perceived quality and outcomes in other surgical settings. In a study by Saarinen et al., more postoperative complications after general and orthopaedic surgery were associated with lower perceived quality of care [17]. Black et al. found a positive association between patient experience and patient-reported outcomes after hip or knee replacement or groin hernia repair [18]. In the large-scale study by Black et al., communication was one of the two aspects of experience that was most related to better outcome (the other was trust in the doctor). Differences between patient groups in the present study and the before mentioned studies could contribute to our results. Orthopaedic patients expect less symptoms after treatment, while surgical prostate cancer patients do not.

Although previous research on experience measures and outcomes after prostatectomy are scarce, there are studies on satisfaction and treatment regret. A long-term follow-up study found that 15% of surgical prostate cancer patients reported treatment regret, and that regret was more common among men that experienced adverse effects [14]. Other researchers reported that erectile dysfunction after prostatectomy was associated with less satisfaction, but also that improved patient education and more information could improve satisfaction [15].

The distinction between experience and satisfaction is difficult. Although PREMs aim to be independent measures, they are, just as satisfaction measures, influenced by outcomes and expectations. Our findings suggest that not only outcomes, but patient-reported symptoms per se have impact on patient-reported experience.

The perceived quality of preoperative information is a structure measure that could identify areas to improve. Despite that the majority rated the information as good in our cohort, a notable share rated the given information as less good. Surprisingly, this was also present for men who reported less symptoms after treatment. There are several possible reasons for this. One explanation could be related to timing of the information. Understandably, the focus for many patients recently diagnosed with cancer is to be cured. The prostate cancer diagnosis is for many men a psychological burden [19], so when they meet their surgeon for planning of treatment, they may not be responsive to information about long-term problems. Consequently, they therefore report the quality of the information as poor if adverse effects emerge later on. This may also apply for men who experienced severe symptoms before treatment and later on reported that their symptoms remained or escalated. Another plausible explanation is that surgeons tend to downplay the risk of adverse effects and their severity to avoid worries or are oblivious to how severe the patients actually perceive their problems. There are several studies showing that clinicians underestimate the severity of their patients' adverse effects [20–23]. This explanation may also apply to the association between worse EPIC scores and poorer ratings of the quality of help received. A third explanation for our findings could be that the surgeons' communication skills were not good enough [24]. They may not have been fully able to capture when patients need help, or to present adverse effects in a way that was understood by the patient. A fourth possible explanation is that men with certain personality traits are more likely to report more severe adverse effects [25] and that these men are also more critical against the information they receive.

Clinical consequences of our results could be to improve urologists' communications skills and the support to men who experience urinary problems, sexual difficulties or other

problems related to prostate cancer and its treatment. Implementation of training programs could be helpful to make urologists attentive on how they communicate and give objective information [26]. It has previously been reported that urologists' communications skills influence prostate cancer patients' treatment choices [27]. Men who experience severe new or remaining problems after treatment should further be encouraged to seek help, and during follow-up the clinicians should be aware of their responsibility to offer help to cope with symptom distress and adverse effects.

A limitation of this study is the single institution design and small sample size. Our results need to be reproduced in multi-institutional and larger scale studies to be generalizable. We also lack information about non-responders. Another limitation is the use of single items and not a validated PREM questionnaire. The selected items have focus on information about and help with adverse effect, hence other aspects of patient-perceived quality of care are not assessed. However, there is no consensus about which PREM questionnaire one should use for prostate cancer patients. In general, PREMs as well as PROMs are often lacking in clinical registries [28], and compared to questionnaires designed for PROMs, there are few validated questionnaires to evaluate PREMs [13]. Another limitation could be recall bias, since the follow-up questions were answered several months after treatment.

5. Conclusions

Patients' perception of the information and the help they received about adverse effects after radical prostatectomy was associated with self-reported symptoms: more symptoms were associated with poorer patient-perceived quality of information. Adverse effects did not explain this finding. Most men who reported rated the information as good, regardless of whether they had more or less symptoms after than before RARP. Our findings suggest a need for improvement on preoperative communication before RARP.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/healthcare10030519/s1, Figure S1: Scatterplot showing the association between EPIC-CP at baseline and follow-up, stratified on how information was rated on the item "I received good information about adverse effects".

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