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Prostate Cancer

Europa Uomo Patient Reported Outcome Study (EUPROMS): Descriptive Statistics of a Prostate Cancer Survey from Patients for Patients

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Abstract

Background: Europa Uomo initiated the Europa Uomo Patient Reported Outcome Study (EUPROMS) to collect prostate cancer (PCa) patient-reported outcome (PRO) data as a primary endpoint.

Objective: To inform future PCa patients about the impact of PCa treatment through self-reported PRO data of fellow patients collected outside a clinical trial setting.

Design, setting, and participants: A cross-sectional survey was conducted among PCa patients currently receiving or having received treatment. The EUPROMS survey contained the EQ-5D-5 L (generic health), the EORTC-QLQ-C30 (cancer-specific quality of life (QoL), and the Expanded Prostate cancer Index Composite short form 26 (EPIC-26; prostate-specific health) questionnaires.

Outcome measurements and statistical analysis: Descriptive statistics were used to assess the demographic and clinical characteristics, and to analyze the PROs of EQ-5D-5 L, EORTC-QLQ-C30, and EPIC-26.

Results and limitations: Between August 21 and November 19, 2019, 2943 men from 24 European countries completed the EUPROMS survey. The median age of the respondents was 71 yr (interquartile range 65–75 yr); 81.9% was living with a spouse. In total, 1937 (65.8%) men underwent a single treatment, and 636 (21.6%), 300 (10.2%), and 70 (2.4%) underwent two, three, and four treatments, respectively. Fatigue scores are highest for men who underwent radiotherapy or chemotherapy. Progression of disease leads to more insomnia. Surgery affects urinary incontinence the most. Self-reported sexual function amounts to 27/100, with the lowest scores being reported for men who underwent surgery and radiotherapy (15/100). Overall, patients who received two or more treatments reported lower scores for all indices.

Conclusions: The EUPROMS survey provided a cross-sectional picture of the current PCa patient population and their reported QoL. Initial treatment is often followed by subsequent treatments, affecting mainly sexual function, as well as fatigue and insomnia. QoL of men undergoing chemotherapy is worse for almost all domains. These data can inform physicians and patients on the true impact of PCa treatment.

Patient summary: Patient-reported quality of life in the Europa Uomo Patient Reported Outcome Study (EUPROMS) survey—a more informal setting as compared with clinical trials—reveals that prostate cancer treatment affects mainly sexual function, fatigue, and insomnia.

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1. Introduction

In many Western countries, the incidence of prostate cancer (PCa) is high and contributing greatly to the cancer disease burden [1–3]. Although the 5-yr PCa-specific survival of localized PCa is >99%, a PCa diagnosis and its subsequent management will impact a man's quality of life (QoL) [2]. The extent of the impact depends on patient characteristics (eg, age, comorbidity, etc.), tumor stage and grade at diagnosis, and the subsequent treatment that is chosen, as well as on the upfront treatment information that patients receive regarding what can be expected in terms of clinical and QoL outcomes. In clinical investigator-initiated trials, patient-reported outcomes (PROs) are often included as secondary endpoints to support and help interpret the primary endpoint [4]. However, instead of PROs being included to support healthcare based on clinical outcomes, these should be viewed as an integral part of healthcare, or as Porter [5] indicates, "PROs are an inherent part of 'value' in the concept of value-based healthcare," in which value is measured by the outcomes achieved and outcomes inherently being condition specific and multidimensional. According to Porter [5], "measuring value should encompass all services or activities that jointly determine success in meeting a set of patient needs". Hence, patient organizations have raised their voices on collecting PROs, as they enable patients to communicate their experiences, assess whether their experiences align with their expectations of treatment, and highlight any unmet needs or care areas that are in need of improvement [4,6,7].

To that end, Europa Uomo, the PCa patient coalition in Europe, initiated the Europa Uomo Patient Reported Outcome Study (EUPROMS), in which collection of PRO data reflecting patients' QoL after PCa treatment is the primary endpoint. The study hypothesized that a difference exists with respect to PRO data published in the scientific literature on clinical-investigator-initiated studies and what they heard back from its members and supporters who underwent PCa treatment. Europa Uomo, therefore, wanted to investigate what the real burden of PCa treatment is, with the aim of informing future PCa patients about the impact of PCa treatment through self-reported PRO data of fellow patients collected outside a clinical trial setting.

2. Patients and methods

2.1. Patient screening criteria

Men were eligible to complete the EUPROMS survey if they were diagnosed with PCa, were currently receiving treatment, or had received treatment for their PCa in the past, including active surveillance (AS), in case they were not affiliated in any way with a pharmaceutical company and did not participate in related research in the past month.

2.2. Recruitment and data collection

The EUPROMS survey was available in 19 languages, via a link placed on the website of the Europa Uomo website (www.europa-uomo.org).

Europa Uomo used its network of, among others, national patient organizations and supportive urologists to promote the EUPROMS survey as well as to stimulate European PCa patients to complete it. Europa Uomo set a target of collecting a minimum of 1000 responses. Data collection was handled by CelloHealth UK to ensure that privacy regulations were complied with.

2.3. PRO measures

A set of validated measures, commonly accepted and used for research purposes, was included in the EUPROMS survey to evaluate generic health (EQ-5D-5L), cancer-specific QoL (EORTC-QLQ-C30), and prostate-specific health (Expanded Prostate cancer Index Composite short form 26 [EPIC-26]).

EQ-5D-5L is a generic measure of health status and consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [8]. Each dimension has five answering options: no problems, and slight, moderate, severe, and extreme problems [9,10]. The EQ visual analog scale (EQ-VAS) is furthermore a part of the EQ-5D-5L and ranges from 0 to 100, with the endpoints labeled as "the best health you can imagine" (score 100) and "the worst health you can imagine" (score 0). Participants are asked to indicate what their current health state is [8–10].

EORTC-QLQ-C30 (version 3.0) incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), a global health status/QoL scale, and a number of single items assessing additional symptoms commonly reported by cancer patients, such as dyspnea, loss of appetite, insomnia, constipation, and diarrhea. Finally, the perceived financial impact of the disease and treatment is assessed [11]. Scale scores were calculated by averaging items within scales and transforming average scores linearly. All the scales range in score from 0 to 100. For the functional scales, a higher score represents a high or healthy level of functioning. For a symptom scale, a high score represents a high level of symptomatology or problems [12].

EPIC-26 was designed to evaluate function and bother after PCa treatment [13,14]. EPIC-26 contains five multi-item domains: urinary incontinence (four items), urinary irritation/obstruction (four items), bowel function (six items), sexual function (six items), and vitality/hormonal function (five items). In addition, a single-item measure of overall urinary bother is included. All domains for EPIC-26 are reported on a 0–100 scale, with higher scores representing favorable health-related QoL [13,14].

2.4. Statistical analysis

Descriptive statistics were used to assess the demographic and clinical characteristics of the men who completed the EUPROMS survey, and to analyze the PROs of EQ-5D-5L, EORTC-QLQ-C30, and EPIC-26. R version 3.5.1 was used to perform all analyses [15].

PRO data were described for the most common treatment modalities reported by the EUPROMS survey participants. For men who underwent a single treatment, this included AS, radical prostatectomy (RP), and radiotherapy (RT). For men who underwent two treatments, it included the combinations of AS + RP, RP + RT, and RT + androgen deprivation therapy (ADT). Furthermore, we described the PRO data for men who indicated to have undergone chemotherapy, either as a single treatment or after having received other treatment(s). For miscellaneous single treatments or combinations of treatments, the numbers were too small to report the PRO data.

3. Results

Between August 21 and November 19, 2019, 2943 of 3983 (74%) men—from 24 European countries—who started

Table 1 – Patient characteristics.

Demographic characteristics	
Age at completing questionnaire, median (IQR)	71 (65–75)
Age at diagnosis (yr), n (%)	
<55	319 (10.8)
55–59	504 (17.1)
60–64	716 (24.3)
65–69	704 (23.9)
70–74	464 (15.8)
75–79	181 (6.2)
80+	55 (1.9)
Age at start first treatment (yr), n (%)	
<55	297 (10.1)
55–59	478 (16.2)
60–64	701 (23.8)
65–69	710 (24.1)
70–74	492 (16.7)
75–79	202 (6.9)
80+	63 (2.1)
Living situation, n (%)	
With spouse	2409 (81.9)
Alone	410 (13.9)
With other family	81 (2.8)
In a care facility	11 (0.4)
Other	32 (1.1)
Last employment (before retirement), n (%)	
Higher managerial	585 (19.9)
Intermediate managerial	1012 (34.4)
Junior managerial	446 (15.2)
Skilled manual worker	343 (11.7)
Semiskilled manual worker	62 (2.1)
Unskilled manual worker	35 (1.2)
Unemployed	43 (1.5)
Other	417 (14.2)
Education, n (%)	
University entrance certificate	915 (31.1)
Entrance certificate for a higher technical college	832 (28.3)
Comprehensive school	397 (13.5)
Intermediate/secondary school	316 (10.7)
Lower secondary school or equivalent	217 (7.4)
Other	250 (8.5)
None	16 (0.5)
Country of residence, n (%)	
Austria	66 (2.2)
Belgium	339 (11.5)
Bulgaria	1 (0.03)
Czech Republic	3 (0.1)
Denmark	188 (6.4)
Estonia	8 (0.3)
Finland	65 (2.2)
France	234 (8.0)
Germany	253 (8.6)
Greece	1 (0.03)
Hungary	10 (0.3)
Ireland	26 (0.9)
Italy	71 (2.4)
Latvia	11 (0.4)
Lithuania	52 (1.8)
Norway	506 (17.2)
Poland	109 (3.7)
Portugal	75 (2.5)
Slovak Republic	8 (0.3)
Spain	55 (1.9)
Sweden	386 (13.1)
Switzerland	7 (0.2)
The Netherlands	244 (8.3)
UK	187 (6.4)
Other (mainly Cyprus)	38 (1.3)
Self-reported tumor characteristics	
T stage, n (%)	
T1	512 (17.4)
T2	1175 (39.9)

T3	561 (19.1)
T4	365 (12.4)
I don't know	330 (11.2)
Gleason score^a, n (%)	
Gleason 6	317 (10.8)
Gleason 7 (3 + 4)	538 (18.3)
Gleason 7 (4 + 3)	355 (12.1)
Gleason 8	278 (9.4)
Gleason 9	284 (9.7)
Gleason 10	22 (0.7)
I don't know	42 (1.4)
Missing	101 (3.4)
Grade Group^a, n (%)	
GG1	75 (2.5)
GG2	134 (4.6)
GG3	193 (6.6)
GG4	121 (4.1)
GG5	56 (1.9)
I don't know	114 (3.9)
Missing	1244 (42.3)
Don't know both Gleason score and grade group, n (%)	1006 (34.2)

GG = grade group.

^a Some knew both their Gleason score and the grade group, some knew only their Gleason score, some knew only their grade group, and some knew neither their Gleason score nor their grade group. Percentage missing is calculated as a proportion of $n = 2943$.

filling in the questionnaire completed the EUPROMS survey on their smartphone, laptop, or computer. In European countries with a somewhat lower per capita income level, local PCa patient organization members offered a workspace for participants to complete the survey, and in some instances, telephone assistance was provided in completing the questionnaire.

The median age of men who completed the survey was 71 yr (interquartile range [IQR] 65–75 yr; Table 1). The majority of men were living with a spouse (81.9%), 69.5% performed managerial work (in their last employment before retirement), and 59.4% were either trained at university or had an entrance certificate for a higher technical college. With respect to tumor characteristics, 39.9% of men indicated that they had T2 disease and 30.4% of men indicated to have Gleason 7 PCa (3 + 4: 18.3%, 4 + 3: 12.1%). A total of 1937 (65.8%) men indicated that they underwent only a single treatment for their PCa, with RP being the most reported single treatment ($N = 1,101$; Fig. 1A). A total of 636 (21.6%) men indicated that they, up to the time of filling in the questionnaire, underwent two treatments. The combination of RP and external beam RT (EBRT) was the most reported treatment ($N = 246$; Fig. 1B). A total of 300 (10.2%) men underwent three treatments and 70 (2.4%) indicated that they underwent four or more treatments.

3.1. EQ-5D-5L

3.1.1. Mobility dimension

A total of 76.2–82.9% of men undergoing a single treatment or two treatments reported no mobility problems. Of the men who underwent chemotherapy, 50.4% reported no problems versus 17.5% who reported slight problems, 19.9% who reported moderate problems, and 12.2% who reported severe or extreme problems (Fig. 2A).

Fig. 1 – Treatment profile of the respondents ($n = 2943$). (A) Men who underwent a single treatment. One of the ten answering options for treatment was “other.” Miscellaneous consists of High-intensity focused ultrasound, cryotherapy, and high-dose rate brachytherapy for which the numbers were too small to present separately. (B) Men who underwent a combination of treatments. Patients could indicate any combination of the ten answering categories available under treatment. Miscellaneous consists of the combinations of treatments, such as AS-RT, for which the numbers were too small to present separately. In Fig. 1B, miscellaneous also holds the category “other.” ADT = androgen deprivation therapy; AS = active surveillance; RP = radical prostatectomy; RT = radiotherapy.

3.1.2. Self-care dimension

Most respondents, undergoing either a single treatment or two treatments, reported no problems with self-care (88.9–96.7%). Of men who underwent chemotherapy, 72.8% reported no problems, 24% reported slight or moderate problems, and 3.2% reported severe or extreme problems (Fig. 2B).

3.1.3. Dimension of usual activities

A total of 71.4–79.9% of men undergoing a single treatment or two treatments reported no problems with their usual activities versus 19–26.9% who reported slight or moderate problems. Among men who underwent chemotherapy, 42.7% reported no problems with their usual activities, 21.5% reported slight problems, 25.2% reported moderate problems, and 10.5% reported severe or extreme problems (Fig. 2C).

3.1.4. Pain/discomfort dimension

A total of 58.5–70.3% of men undergoing a single treatment or two treatments reported no pain/discomfort, while 28.3–39.8% reported slight or moderate pain/discomfort. Of men who underwent chemotherapy, 61.8% reported slight or moderate pain/discomfort and 9.7% reported severe/extreme pain/discomfort (Fig. 2D).

3.1.5. Anxiety/depression dimension

A total of 53.2–64.1% of men undergoing a single treatment or two treatments reported no anxiety/depression versus 33.3–42.1% of men who reported slight or moderate anxiety/depression. Among men who underwent chemotherapy, 39.8% reported no anxiety/depression and 32.5% reported slight, 15.9% moderate, and 11.7% severe or extreme anxiety/depression (Fig. 2E).

The median EQ-VAS score for all 2943 men is 80.0 (IQR 65.0–90.0).

Fig. 2 – EQ-5D-5 L dimension scores: (A) mobility, (B) self-care, (C) usual activities, (D) pain/discomfort, and (E) anxiety/depression. ADT = androgen deprivation therapy; AS = active surveillance; RP = radical prostatectomy; RT = radiotherapy.

3.2. EORTC-QLQ-C30

With respect to the functional symptom scores, no big impairments for self-reported functioning are seen. Effects of RT are seen on self-reported fatigue and insomnia scores. Men who ever had chemotherapy reported the highest levels of fatigue and insomnia (Table 2).

3.3. EPIC-26

Effects of treatment are mainly seen on the urinary incontinence and sexual function domains (Fig. 3A–E).

The median scores for self-reported urinary incontinence are lowest for men who underwent RP (71.0, IQR 46.0–100.0), a combination of RP and RT (73.0, IQR 46.0–93.8), or a combination of AS and RP (64.8, IQR 37.5–91.8; Fig. 3A).

The median score for self-reported sexual function is highest for men following an AS management strategy (57.0, IQR 26.3–83.3). Men who underwent RP report a median sexual function score of 20.8 (IQR 8.3–44.5), while the scores were 15.3 (IQR 4.5–32.0) for a combination of RP and RT, 17.3 (IQR 9.7–40.3) for RT, 18.1 (IQR 8.3–36.2) for a combination of RT and ADT, and 26.3 (IQR 8.3–55.9) for a combination of AS and RP (Fig. 3D).

4. Discussion

To the authors' knowledge, this is the first time that the authentic PCa patient voice has been heard in such detail and volume across Europe. A total of 2943 men from 24 European countries completed the EUPROMS survey, and the collected data provide a cross-sectional picture of the current PCa patient population and their self-reported QoL. The data reveal that treating PCa is, in general, not a one-time event. Initial treatment is very often followed by subsequent treatments, all of which have an impact on the QoL of these men over a long period of time. PRO data on sexual function indicate that men who received any active PCa treatment reported a detrimental loss of sexual function; for men who underwent surgery (either alone or in combination with another treatment option), sexual function is affected the most (RP: 20.8, RP + RT: 15.3). Increased levels of fatigue and insomnia are other important effects, which are higher for men who underwent RT or chemotherapy. Chemotherapy (either as single treatment or as a combination of treatments) is related to worse QoL outcomes on many of the generic and disease-specific domains, and hence should be chosen with caution.

Men receiving chemotherapy are in a rather late state of the disease. Early detection of PCa through individualized risk-stratified screening may limit the number of late status, more aggressive PCa diagnosed, and hence the number of men needing chemotherapy. Early detection of PCa has its pros and cons, but it has been shown to reduce the rate of metastatic disease by 42% for men actually screened in the European Randomized study of Screening for Prostate Cancer (ERSPC) [16]. In a later analysis by Buzzoni et al [17], it

Table 2 – EORTC-QLQ-C30 scales.

	AS (N = 179)	AS-RP (N = 60)	RP (N = 1101)	RP-RT (N = 246)	RT (N = 304)	RT-ADT (N = 126)	Chemo (N = 246)
Functional scales ^a , median (IQR)							
Physical	100.0 (86.7–100.0)	93.3 (86.7–100.0)	100.0 (86.7–100.0)	93.3 (86.7–100.0)	93.3 (80.0–100.0)	93.3 (80.0–100.0)	80.0 (60.0–93.3)
Role	100.0 (83.3–100.0)	100.0 (66.7–100.0)	100.0 (83.3–100.0)	100.0 (83.3–100.0)	100.0 (83.3–100.0)	100.0 (66.7–100.0)	66.7 (33.3–100.0)
Cognitive	83.3 (83.3–100.0)	83.3 (66.7–100.0)	100.0 (83.3–100.0)	91.7 (83.3–100.0)	83.3 (83.3–100.0)	83.3 (66.7–100.0)	83.3 (66.7–100.0)
Emotional	91.7 (66.7–100.0)	91.7 (64.6–100.0)	91.7 (75.0–100.0)	91.7 (75.0–100.0)	83.3 (72.9–100.0)	83.3 (66.7–100.0)	75.0 (58.3–91.7)
Social	100.0 (83.3–100.0)	83.3 (66.7–100.0)	83.3 (66.7–100.0)	83.3 (66.7–100.0)	83.3 (66.7–100.0)	83.3 (66.7–100.0)	66.7 (33.3–83.3)
Symptom scales ^a , median (IQR)							
Fatigue	11.1 (0.0–33.3)	11.1 (0.0–33.3)	11.1 (0.0–33.3)	22.2 (0.0–33.3)	22.2 (0.0–33.3)	22.2 (11.1–33.3)	33.3 (22.2–55.6)
Pain	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	25.0 (0.0–50.0)
Nausea and vomiting	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–16.7)
Single items ^a , median (IQR)							
Dyspnea	0.0 (0.0–33.3)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	33.3 (0.0–33.3)
Loss of appetite	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–33.3)
Insomnia	0.0 (0.0–33.3)	33.3 (0.0–33.3)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	33.3 (0.0–33.3)	33.3 (0.0–33.3)	33.3 (0.0–66.7)
Constipation	0.0 (0.0–16.7)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–33.3)	0.0 (0.0–0.0)	0.0 (0.0–33.3)
Diarrhea	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	0.0 (0.0–33.3)
Financial difficulties	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–33.3)

ADT = androgen deprivation therapy; AS = active surveillance; IQR = interquartile range; RP = radical prostatectomy; RT = radiotherapy.

^a All the scales range in score from 0 to 100. For the functional scales, a higher score represents a high or healthy level of functioning. For a symptom scale and the single items, a high score represents a high level of symptomatology or problems.

was shown that the decrease in metastatic disease at diagnosis is the major determinant of the PCa mortality reduction in the ERSPC. In addition to looking at the impact of metastatic disease on mortality, it is important to consider the impact of metastases and subsequent treatment on QoL too. You would rather not have a disease progress to a metastatic stage, not only in terms of survival, but also in terms of QoL experienced by patients.

International guidelines nowadays highlight the importance of shared decision-making for PCa treatment, especially for localized PCa where the available treatment options show very similar survival rates, making a treatment decision a preference-sensitive one [18–22]. For patients to engage actively in shared decision-making, it is important that they have access to information about the expected impact of treatment on both mortality and morbidity. In the study by Wollersheim et al [23], unmet expectations in localized PCa patients were examined as well as their association with decision regret 12 mo after treatment, while having received information on RP, EBRT, and brachytherapy after diagnosis and before being invited and included into the study. The information on the treatments of localized PCa was based on the available scientific

literature. Unmet expectations were defined as the proportion of patients who experienced side effects of treatment as worse than expected. Twelve months after treatment, 71% (210/296) of patients in the study reported at least one unmet expectation. A total of 56% of patients reported worse than expected erectile problems, 29% reported a worse than expected recovery period, 28% reported worse than expected urinary problems, 24% reported worse than expected fatigue, and 17% reported worse than expected bowel problems [23]. Wollersheim and colleagues [23] found that having a passive role in the decision-making process as well as scoring higher on the decision conflict scale (ie, experiencing more uncertainty about the treatment decision) was associated with more unmet expectations. Moreover, unmet expectations were subsequently associated with decision regret [23]. The self-reported QoL of patients in the EUPROMS survey can be of aid in informing fellow patients about what to expect after PCa treatment in terms of QoL, and hence has the potential to lower treatment decision regret. In the EUPROMS survey, the self-reported sexual function scores, especially for men who underwent active treatment, were low (ie, RP: 20.8, RP + RT: 15.3, RT: 17.3, RT + ADT: 18.1, AS + RP: 26.3). On average,

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Fig. 3 – EPIC-26 domain scores: (A) urinary incontinence domain, (B) urinary obstructive domain, (C) bowel domain, (D) sexual function domain, and (E) hormonal domain. ADT = androgen deprivation therapy; AS = active surveillance; EPIC-26 = Expanded Prostate Cancer Index Composite short form 26; RP = radical prostatectomy; RT = radiotherapy.

50% of men indicated that their lowered sexual function is a moderate or big problem for them. If we compare these numbers with, for instance, the self-reported QoL of men who underwent RP or RT in the ProtecT study, then at 48 mo sexual function scores reach a stable level of around 30 for men who underwent RP and 35 for those who underwent RT [24]. In the review by Loi et al [25], studies evaluating sexual function of men who underwent stereotactic RT reported median sexual function scores between 35 and 77 at the time of treatment and 60-mo of follow-up. These are quite large differences that warrant further analyses. It might be that the data currently underlying the concept of “value” in value-based healthcare might not represent the true burden experienced by patients. However, for value-based healthcare to succeed, the “value” must be reflective of the true outcomes, in terms of both near-term and longer-term health [5]. This highlights the importance of the results of this survey and the need to understand the differences from PRO-data currently available from clinical investigator-initiated trials.

There are strengths and limitations in the conduct of the EUPROMS study. A strength is the large patient sample of nearly 3000 men who completed the EUPROMS questionnaire in roughly 3 mo of time, indicating that patients are willing to share their experiences associated with PCa treatment for fellow future patients to learn from. Furthermore, the EUPROMS survey contained validated PRO measures that cover the domains most relevant to patients. A limitation is that no pretreatment PRO data are available for the study population. Furthermore, in Table 1 it was seen that 11% of respondents were not aware of their T stage and a large share was not aware of their Gleason grade or grade group. This may have affected respondents' understanding of certain PCa constructs, such as the difference between AS and watchful waiting, or whether their cancer recurred. Enhanced information provision and patient-doctor communication may overcome such a knowledge gap. For men who underwent RP, either as a single treatment or in a combination of treatments, it is unknown whether they were treated with the nerve-sparing procedure or not. Finally, 59.4% of respondents had higher educational levels (university or entrance certificate for a higher technical college), which is likely not representative of the educational levels of the general population.

5. Conclusions

In the EUPROMS study, initiated by the PCa patient coalition Europa Uomo, 2943 men from 24 European countries provided a cross-sectional picture of the current PCa patient population and their reported QoL. Initial treatment is often followed by subsequent treatments, affecting mainly sexual function, as well as fatigue and insomnia. QoL of men undergoing chemotherapy is worse for almost all measured domains. Self-reported scores of the EUPROMS study differ greatly from those of clinical studies such as ProtecT and hence should be analyzed further. Meanwhile, data from the EUPROMS study can be used in daily clinical practice to

inform physicians and patients about the true impact of PCA treatment.

Author contributions: Lionne D.F. Venderbos had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Venderbos, Remmers, Roobol, Deschamps.

Acquisition of data: Deschamps, Dowling, Carl.

Analysis and interpretation of data: Venderbos, Remmers, Roobol, Deschamps.

Drafting of the manuscript: Venderbos, Remmers.

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Statistical analysis: Remmers, Venderbos.

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