Health-related Quality of Life in long-term Prostate Cancer Survivors after Nerve-Sparing and Non-Nerve-Sparing Radical Prostatectomy – Results from the multiregional PROCAS study

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Abstract

Background: Nerve-sparing (NS) surgery was developed to improve postoperative sexual and potentially urological outcomes after radical prostatectomy (RP). However, it is largely unknown how NSRP affects health-related quality of life (HRQoL) including urinary and sexual outcomes in prostate cancer (PC) survivors 5-10 years after diagnosis in comparison to Non-NSRP.

Methods: The study population included 382 stage pT2-T3N0M0 PC survivors 5-10 years post-diagnosis, who were identified from the multiregional Prostate Cancer Survivorship in Switzerland (PROCAS) study. Briefly, in 2017/2018, PC survivors were identified via six population-based cancer registries based in both German- and French-speaking Switzerland. HRQoL and PC-specific symptom burden was assessed using the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires. Differences in HRQoL outcomes between survivors treated with NSRP (uni- & bilateral) and Non-NSRP were analysed with multivariable linear regression adjusted for age, years since diagnosis, cancer stage, comorbidities at diagnosis and further therapies, if appropriate. Multiple imputation was performed to minimize the bias due to missing data.

Results: 5-10 years after diagnosis, PC survivors treated with NSRP and Non-NSRP reported similar symptom burden and comparable HRQoL function scores. The only significant differences were reported for sexual activity, whereas PC survivors who underwent NSRP reported statistically significant (p=0.031) higher sexual activity than those on Non-NSRP. NSRP and Non-NSRP reported similar scores for urinary symptoms and all other HRQoL outcomes.

Conclusions: NSRP and Non-NSRP were generally associated with comparable long-term HRQoL outcomes, but NSRP was linked with significantly higher sexual activity scores than Non-NSRP. Our results support nerve-sparing techniques as an option to improve post-operative sexual but not urinary outcomes after RP in long-term PC survivors.

Introduction

Although radical prostatectomy (RP) is the most common treatment strategy for men diagnosed with prostate cancer (PC) [1], the survival benefit for PC survivors treated with RP compared to other
primary management options remains unclear [2–4]. In addition, RP may have strong both acute and long-lasting detrimental effects, notably on urinary and sexual functioning [5–7].

Nerve-sparing (NS) technique was developed to improve postoperative sexual function (SEF) [8] and potentially urinary outcomes after RP. Indeed, higher recovery rates of SEF after nerve-sparing RP compared to non-nerve-sparing (Non-NS) RP could be observed up to 24 months [9,10]. However, a positive effect for postoperative urinary outcomes remains controversial [11,12]. A systematic review published in 2015 concluded that preservation of the neurovascular bundles improves urinary continence in the first six months after surgery, but no effect was seen for later time points up to five years after treatment [13].

Even though extensive research was performed regarding whether NSRP improves urinary outcomes and SEF compared to Non-NSRP in the first time 6–24 months after the operation, little attention has been given to long-term effects. Also research regarding whether NSRP compared to Non-NSRP affects general health-related quality of life (HRQoL) remains limited. To the authors’ knowledge only one study from the United States [14] has assessed HRQoL domains (physical functioning and mental health) and disease-specific symptom burden in PC survivors up to 10 years after diagnosis either treated with NSRP or Non-NSRP. In this longitudinal study, PC survivors treated with Non-NSRP reported similar declines at five years after diagnosis in physical functioning, mental health and urinary continence scores compared to survivors treated with NSRP but significantly stronger declines in SEF scores. However, no study assessed further HRQoL functions and cancer and treatment-related symptom burden beside urinary outcomes and SEF in long-term PC survivors. Therefore, the objective of our study was to identify differences and similarities in general HRQoL and PC-specific symptom burden by NSRP (uni/bilateral) and Non-NSRP in long-term PC survivors.

Materials And Methods

Study design and study population

Participants were included from the multi-regional Prostate Cancer Survivorship in Switzerland (PROCAS) cohort. In short, the PROCAS study included 748 long-term PC survivors who were diagnosed between 2006 and 2011 and aged 42–75 years at diagnosis. They were identified via six
population-based cancer registries (Cancer Registry Fribourg, Cancer Registry Basel, Cancer Registry Graubünden and Glarus, Cancer Registry East Switzerland, Valais Cancer Registry & Cancer Registry Zurich and Zug) covering an underlying population of 3,456,020 million inhabitants, based in both German and French-speaking Switzerland and invited via their referring urologists. Data collection was conducted between 2017 and 2018 by postal questionnaire. Non-respondents received one reminder. Among PC survivors, 8,712 fulfilled the inclusion criteria for the study (Figure 1). Out of them, 1,246 PC survivors were randomly selected for participation. 1,194 could be contacted and received an invitation. Finally, 748 returned a completed questionnaire (response rate: 62.2%). This analysis was restricted to PC survivors 1) staged pT2-T3 N0 and M0 (according to the TNM classification system published by the American Joint Committee on Cancer have been available in the FCD since 2002[15]), 2) treated with RP as primary therapy and 3) recruited from cancer registries (Cancer Registry Graubünden and Glarus, Cancer Registry East Switzerland, Valais Cancer Registry & Cancer Registry Zurich and Zug), which provided information on degree of NSRP (N = 382).

**Study measures**

**HRQoL and PC-specific symptom burden**

HRQoL and PC-specific symptom burden were assessed with internationally validated instruments: the EORTC QLQ-C30 and the PC specific module QLQ-PR25. The EORTC QLQ-C30 questionnaire consists of 30 items, comprising five functioning scales, a global health/quality of life (QoL) scale, and nine items/scales on symptoms and financial difficulties. The PC-specific EORTC QLQ-PR25 questionnaire consists of 25 questions, assessing urinary and bowel symptoms, sexual activity, sexual functioning and hormonal treatment-related symptoms. Scoring of all instruments was performed according the pertinent scoring manuals [28,31]. High scores on the functioning scales and global health/QoL indicate better functioning and better health, respectively. For the symptom and financial difficulty scales, a higher score represents a greater symptom burden and financial difficulty. High scores in the EORTC QLQ-PR25 represent a greater symptom burden or a better sexual functioning and more sexual activity.

**Demographics, lifestyle and clinical data**
Information whether patients were treated with NSRP and whether it was uni- or bilateral NSRP were provided by the treating urologist, together with the cantonal cancer registries. Physicians also gave detailed information on other treatments, disease progression/relapse (including biochemical and clinical recurrence and metastasis after diagnosis of primary tumour at time of survey) and other primary tumours. Cancer registries provided demographic parameters and clinical information such as date of birth, date of diagnosis and cancer stage. Self-reported demographic included education, living with partner, working status, weight, height and nationality. Questionnaires and all other study documents were available in German, French and Italian.

Statistics
For descriptive purposes, we compared Non-NSRP (n = 167) vs. NSRP (n = 215) by several clinical and sociodemographic characteristics. The group NSRP consisted of PC survivors treated with both uni- and bilateral NSRP, as these two groups did not differ with respect to clinical and sociodemographic characteristics (Table S1) and reported similar HRQoL outcomes (Tables S2). Adjusted means based on multivariable linear regression models were calculated to describe and test for differences in HRQoL. Models were adjusted for age at survey, years since diagnosis, cancer stage at diagnosis, comorbidities at diagnosis and further therapy (during 1st year after diagnosis) if appropriate. Other variables including education, working status, nationality and language were considered as additional potential confounders but not included as they did not improve the model fit. Multiple Imputation Chained Equations (MICE) procedure with 25 repetitions was employed to reduce possible bias due to missing values. Differences in mean HRQoL scores larger than 10 points were considered clinically meaningful [18]. A p-value <0.05 (two-sided) was considered statistically significant. The p-values were not adjusted for multiple testing, so the p-values refer to the individual tests rather than a global test for differences. All analyses were performed using STATA statistical software (Version 15.1).

Results
Overall, from 382 PC survivors included in this analysis 56.3 %, received NSRP and 43.7 % Non-NSRP (Table 1). Mean age was 72.4 years and mean time since diagnosis was 7.5 years. Participants had
mainly Swiss nationality and filled-in the German questionnaire. Beside years since diagnosis \( (p<0.026) \) and disease progression \( (p<0.029) \), clinical and demographic characteristics were comparable among PC survivors by treatment strategy. For PC survivors treated with Non-NSRP mean time since diagnosis was 7.8 years, whereas it was 7.4 years for PC survivors treated with NSRP. Moreover, disease progression/relapse was more likely among participants on Non-NSRP (28.8% vs. 17.7%).

Multiple imputation did not substantially alter the distribution of Non-NSRP and NSRP (Table S3) and their association with baseline clinical and demographic characteristics (Tables S4) and HRQoL outcomes (Table S5).

**HRQoL and PC-specific symptom burden of PC survivors treated with Non-NSRP vs. NSRP**

In general, PC survivors reported excellent functioning and good general health/overall quality of life. Adjusted mean scores of all functioning scales were comparable between PC survivors who have received Non-NSRP and NSRP (Figure 2, all \( p \)-values > 0.05).

Fatigue, insomnia and pain were the symptoms with the highest reported burden among all PC survivors. However, differences in adjusted mean scores between patients treated with Non-NSRP and NSRP were small (max. 2.8 scale points) and not statistically significant (Figure 3, all \( p \)-values > 0.05). PC survivors who underwent NSRP reported statistically significant \( (p = 0.031) \) higher sexual activity (not clinically significant different) but similar sexual functioning compared to those who have received Non-NSRP (Figure 4). Regarding urinary symptoms and urinary bother no significant different mean scores were reported.

In supplemental subgroup analysis no difference in urinary symptoms, urinary bother nor sexual activity and sexual function was observed when we compared HRQoL and PC-specific symptom burden of PC survivors treated with unilateral NSRP vs. bilateral NSRP (Table S2).

**Discussion**

Given the increasing numbers of long-term PC survivors [19], it is imperative to understand whether treatment modalities such as NSRP may result in long-lasting health benefits including better HRQoL...
and lower PC-specific symptom burden. This population-based study suggests, however, that HRQoL and symptom burden in PC survivors 5–10 years after diagnosis of localized PC in general does not vary according to type of surgery (NSRP versus Non-NSRP) except for the finding that PC survivors who underwent NSRP were significantly more sexually active than those treated with Non-NSRP.

In general, the results from our cross-sectional survey confirm and extend the results of the longitudinal survey based on the CaPSURE registry [14]. In addition to the results from the CaPSURE registry which described differences in SEF but comparable physical and mental health in PC survivors after NSRP and Non-NSRP, there appears to be no further differences between the two treatment groups with respect to global health status, role, emotional, cognitive and social functioning as well as burden of fatigue, insomnia, dyspnoea, constipation and pain according to our study.

Previous studies have reported that NSRP improves postoperative sexual function up to five [9,10,20] and 10 years after diagnosis [14] compared to Non-NSRP. In our study, no significant differences for SEF were reported, but patients treated with NSRP scored significantly higher on all sexual activity scales. The discrepancy between our results and the aforementioned studies are potentially based on the usage of different instruments to assess PC-specific symptom burden. In this study the EORTC-PR25 questionnaire was used whereas the other studies used the UCLA-PCI and the EPIC–26 questionnaire. In the EORTC-PR25 sexual activity is measured with two questions, which are asking about sexual interest and frequency of sexual activity. Only patients who were sexually active (183/382) answered the additional questions on the ability to have an erection and orgasm, and sexual desire [17], which correspond to the SEF domain. In contrast, all these items including level of sexual activity are part of the SEF domain in the other two instruments [21]. Therefore, results regarding SEF from studies using different QOL instruments are not directly comparable.

Nevertheless, our results may have clinical implications. As most PC survivors have very good survival perspectives and are living with their partners, the finding that NSRP results in favourable sexual function even 5–10 years after diagnosis might have an impact on the treatment decision-making process.

The lack of differences with respect to long-term urinary symptoms and urinary bother might be
surprising but our results are similar to another study performed in Switzerland [12], even though studies differ methodologically. The latter study continuously assessed and compared urinary incontinence over a 10 years period in PC survivors either treated with NSRP or Non-NSRP. This study was conducted in a canton, which was not part of this study, and adjusted its models for factors (such as PC volume, clinical risk group, positive margins and preoperative urinary incontinence score and PSA-values), which were not assessed in our study. Beside those differences, the similarity of the results supports the conclusion of the other study, stating that NSRP should not be conducted with the primary aim to improve urinary outcomes.

To our knowledge, this is the first study performed in Europe which compared HRQoL and PC-specific symptom burden according to NS surgery in long-term PC survivors, using a multiregional-based design, including patient recruitment via multiple population-based cancer registries in two different language regions. Beside these strengths, there are limitations which need to be discussed. For example, not in all study regions information were available whether participants received NSRP. Therefore, participants of two study regions were excluded from this analysis. Moreover, although we corrected our models for a range of clinical and sociodemographic variables, we did not have all information such as clinical risk group, the degree of nerve sparing, urinary outcome scores and most importantly baseline SEF, which might have influenced either the treatment choice or the outcome. Finally, information on whether RP was performed open or robotic-assisted were not assessed in the study, what might also influence the generalizability of our results, even though these two techniques yielded similar functional outcomes in short-term PC survivors as seen in randomized controlled trials [22].

Conclusion
In conclusion, NSRP was generally associated with comparable long-term HRQoL outcomes but higher sexual activity scores when compared to Non-NSRP. Our results support nerve-sparing techniques as an option to improve post-operative sexual but not urinary outcomes after RP in PC survivors.

Abbreviations
HRQoL—Health-related Quality of Life
PC—Prostate Cancer

PNS cluster—Psycho-neurological Symptom Cluster

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Declarations
Ethics approval and consent to participate
The PROCAS study has been approved as a multi-centre study by the Ethics Committee Zurich and by
all reviewer boards accountable for the participating cancer registries (BASEC Number: 2016–00608).

Consent for publication

“Not applicable”

Availability of data and materials

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

SA & VA developed the study concept. SA, VA, EMD and HPS were responsible for the study design. Date acquisition was performed by SA, EMD, BC, CEH, IK, SMM; CH, SR, MQ, KS, RTS, MR, HJ, HPS & VA.

SA performed the statistical analysis. SA and VA wrote the manuscript. All authors read, commented and approved the final manuscript.

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Tables
Table 1: Demographic and clinical characteristics of PC survivors by nerve-sparing status (after multiple imputation of missing values).

|                              | Total (n=382) | Non-NSRP (n=167) | NSRP (n=215) | Non-NSRP \(^1\) |
|------------------------------|--------------|------------------|--------------|----------------|
| Age at survey                |              |                  |              |                |
| <70 years                    | 30.4         | 29.6             | 31.7         |                |
| 70-74 years                  | 32.2         | 31.1             | 33.0         |                |
| 75-79 years                  | 25.1         | 25.0             | 25.2         |                |
| ≥80 years \(\text{Mean (SD)}\) | 12.3         | 15.2             | 10.1         | 0.23          |
| Col%                         |              |                  |              |                |
| Education (highest degree)   |              |                  |              |                |
| Low                          | 0.8          | 0.6              | 0.9          |                |
| Medium                       | 51.2         | 50.3             | 51.8         |                |
| High                         | 48.0         | 49.1             | 47.3         | 0.57          |
| Nationality Swiss (yes)      | 95.5         | 96.0             | 95.2         | 0.75          |
| Language questionnaire       |              |                  |              |                |
| German                       | 94.8         | 97.0             | 93.0         | 0.12          |
| French/Italian               | 5.2          | 3.0              | 7.0          | 0.19          |
| Living with partner (yes)    | 82.3         | 78.1             | 85.5         |                |
| Working at survey (yes)      | 11.8         | 10.4             | 12.9         | 0.52          |
| Body-Mass-Index              |              |                  |              |                |
| <18.5                        | 0.3          | 0.6              | 0.0          |                |
| 18.5–24.9                    | 35.1         | 31.1             | 38.0         |                |
| 25.0–29.9                    | 52.0         | 51.6             | 51.6         |                |
| ≥30                          | 12.6         | 16.8             | 10.4         | 0.21          |
| Cancer stage                 |              |                  |              |                |
| pT2N0M0                      | 77.4         | 72.8             | 82.0         | 0.08          |
| pT3N0M0                      | 22.6         | 27.2             | 18.0         |                |
| Years since diagnosis        |              |                  |              |                |
| 5-6                          | 27.2         | 22.3             | 31.0         |                |
| 7-8                          | 46.1         | 43.8             | 47.8         |                |
| 9-10                         | 26.7         | 33.9             | 21.1         |                |
| Mean (SD) \(\text{SD}\)     | 7.5 (1.4)    | 7.8 (1.5)        | 7.4 (1.5)    | 0.02          |
| Disease progression/relapse  |              |                  |              |                |
| (yes)                        | 22.0         | 28.4             | 17.7         | 0.02          |
| Comorbidities at diagnosis   |              |                  |              |                |
| 0                            | 72.4         | 80.0             | 66.9         |                |
| 1                            | 19.1         | 12.2             | 24.2         |                |
| ≥2                           | 8.5          | 7.8              | 8.9          | 0.09          |
| Further therapy (during 1st year after diagnosis) |     |                  |              |                |
| External-beam radiation therapy | 6.6         | 7.8              | 5.6          | 0.58          |
| Hormone therapy              | 4.0          | 4.3              | 3.7          | 0.85          |

Col. – Column

1 Education: Low (no or primary school); Medium (lower general secondary education or vocational training); High (pre-university education, high vocational training, university)

Figures
Figure 1

Study Flow Chart
Mean scores of EORTC QLQ-C30 HRQoL scales of PC survivors by nerve-sparing status (after multiple imputation of missing values). A high score represents a high/healthy level of functioning/high QoL. Mean scores were adjusted for age at survey, years since diagnosis, cancer stage, comorbidities at diagnosis and further therapy if appropriate. I bars represent ± standard errors; all p-values > 0.05
Figure 3
Mean scores of EORTC QLQ-C30 symptom scales of PC survivors by nerve-sparing status (after multiple imputation of missing values). A high score represents a high symptom burden. Mean scores were adjusted for age at survey, years since diagnosis, cancer stage, comorbidities at diagnosis and further therapy if appropriate. I bars represent ± standard errors; all p-values > 0.05
Figure 4

Mean scores of EORTC PR25 scales of PC survivors by nerve-sparing status (after multiple imputation of missing values). A high score represents higher symptom burden or higher sexual activity/better sexual functioning. Mean scores were adjusted for age at survey, years since diagnosis, cancer stage, comorbidities at diagnosis and further therapy if appropriate. 1 lower sample size as questions regarding these functions were conditional – urinary bother (n=104) & sexual functioning (n=183) I bars represent ± standard errors; all p-values > 0.05 if not indicated otherwise

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.
20190714_supplementary material_PROCAS_NSRP.pdf