

Health-related quality of life in prostate cancer patients in the Silesian Province (Poland) before and after radical prostatectomy – a longitudinal observational pilot study

Tomasz Jurys^{1,A-F®}, Bartłomiej Burzyński^{2,A-B,D-F®}, Andrzej Kupilas^{3,A-F®}

- ¹ Doctoral School, Faculty of Health Science, Medical University of Silesia, Katowice, Poland
- ² Department of Rehabilitation, Faculty of Health Sciences, Medical University of Silesia, Katowice, Poland
- ³ Department of Urology and Urooncology, Medical Hospital, Gliwice, Poland
- A Research concept and design, B Collection and/or assembly of data, C Data analysis and interpretation,
- D Writing the article, E Critical revision of the article, F Final approval of the article

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Abstract

Introduction. In recent years, patient-reported outcomes have played an increasingly important role in the evaluation of the effectiveness of treatments as aspects of health-related quality of life (e.g. physical, emotional, and psychosocial), and are taken into account in the selection of treatment methods and complementary management (e.g. nursing care or physiotherapy).

Objective. The aim of this pilot study was to assess changes in the health-related quality of life in a prostate cancer population before and 3 months after radical prostatectomy. The main motivation for the study is the small number of studies using validated tools to assess the quality of life of men in the Polish population suffering from prostate cancer.

Materials and method. The study concerned 31 newly-diagnosed prostate cancer patients who qualified for radical prostatectomy. Quality of life assessment was performed twice – first before surgery, and then 3 months afterwards – using the EORTC OLO-C30 and EORTC OLO-PR25 questionnaires.

Results. Comparison of baseline and 3-month follow-up results revealed significant deteriorations in patients' quality of life across various domains, with the clinically and statistically most significant changes being observed on the emotional, social, and role functioning scales.

Conclusions. Radical prostatectomy contributed to decreased quality of life 3 months postoperatively. The psychosocial domains of the quality of life are more strongly affected than the physical domains.

Key words

quality of life, prostate cancer, prostatectomy

INTRODUCTION

In recent years, the incidence of prostate cancer (PCa) has been growing globally. As a result, prostate cancer is now among the top five cancers in terms of incidence and the top ten in terms of mortality worldwide [1, 2]. The highest percentage of men suffering from prostate cancer is found in Europe, while the highest mortality rate is observed in Asian countries [1, 2, 3]. Detailed data on prostate cancer incidence, mortality, and 5-year prevalence rates in different regions of the world are presented in Table 1. Prostate cancer is currently the most frequently diagnosed malignant neoplasm occurring in men in Poland, accounting for 20.6% of such diagnoses. The death rate due to prostate cancer is close to 10.3% [4].

Research on population migration has revealed the importance of lifestyle and environmental factors in the development of prostate cancer. Currently well-established risk factors are age, race, and family history [2, 3]. There are no well-established modifiable factors associated with a

Address for correspondence: Tomasz Jurys, Doctoral School, Faculty of Health Sciences, Medical University of Silesia, Katowice, Poland E-mail: jurystomek3@gmail.com

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Table 1. Prostate cancer incidence, mortality and 5-year prevalence worldwide (source: GLOBOCAN 2020 [1])

	Incidence		Morta	ality	5-year prevalence		
	N	%	N	%	N	%	
Europe	473,344	33.5	108,088	28.8	1,873,814	37.8	
Asia	371, 225	26.2	120,593	32.1	1,176,781	23.7	
North America	239,574	16.9	37,192	9.9	929,921	18.8	
Latin America and the Caribbean	214,522	15.2	57,415	15.3	709,119	14.3	
Africa	93,173	6.6	47,249	12.6	178 ,197	3.6	
Oceania	22,421	1.6	4,767	1.3	89,069	1.8	

higher risk of prostate cancer, but they are likely to include obesity, alcohol consumption, tobacco smoking, and a dairyrich diet. On the other hand, factors likely to reduce the risk of developing the disease include regular physical activity, a diet rich in carotenoid lycopene, and consumption of coffee [2, 3, 5].

Radical prostatectomy is a form of surgical treatment typically adopted in cases of organ confined prostate cancer [6], and involves ablation of the prostate gland with surrounding tissues, seminal vesicles, and sometimes the pelvic lymph nodes [6, 7]. Surgical techniques may be classified as 'open' (radical perineal prostatectomy, radical retropubic prostatectomy) or minimally invasive (robot-assisted radical prostatectomy, laparoscopic radical prostatectomy) [6, 7, 8].

Changes in the quality of life are commonly observed in men with prostate cancer [9]. As early as the point of diagnosis, reduction in the quality of life may be observed on the emotional, cognitive and social levels, among others [10]. This reduction not only results from the fact that patients are confronted with the disease itself, but is also associated with patients' beliefs, and the beliefs of those in their immediate environment, resulting from their understanding of prostate cancer and its treatment [9, 10, 11]. Quality of life has therefore become not only an integral part of the comprehensive assessment of cancer treatment outcomes, but also an important component in the treatment selection itself. Moreover, assessment of the quality of life can be used in the preparation of appropriate care plans for cancer patients, taking into account their individual needs and expectations [11, 12].

OBJECTIVE

The aim of this pilot study was to assess health-related quality of life changes in the prostate cancer population before and 3 months after radical prostatectomy. The main motivation for the is the small number of studies using validated tools to assess the quality of life of men in the Polish population suffering from prostate cancer.

MATERIALS AND METHOD

Study design and population. The study is a prospective longitudinal observational study of a descriptive character concerning newly-diagnosed prostate cancer patients who have undergone radical prostatectomy (open and laparoscopic). The study was conducted between April 2021 – March 2022 at two hospitals in the Silesian Province (Poland). Patients who had given written informed consent were asked to complete two self-administered questionnaires, the first 1–2 days before radical prostatectomy and the second 3 months afterwards.

Inclusion criteria: diagnosis of prostate cancer confirmed by histopathological examination; determination of the grade of prostate cancer by means of Gleason score; no distant metastasis; qualification for radical prostatectomy; no other forms of treatment before radical prostatectomy. Exclusion criteria: patients who: did not meet the inclusion criteria; had been treated for other cancers during the preceding 5 years; opted to resign from participation in the study. The design and all procedures of the study were approved by the Bioethics Committee of the Medical University of Silesia in Katowice (Resolution No. PCN/0022/KBI/111/20).

Quality of life and medical data. In patients who qualified for the study, an analysis of medical documentation was performed, before and after surgery. The following medical records were analyzed: type of surgery; Gleason score; PSA level; stage of tumour; comorbidities.

The survey used Polish-language versions of the standardized and validated questionnaires EORTC QLQ-C30

(European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Items) and EORTC QLQ-PR25 (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Prostate 25 Items). The use of these questionnaires has been approved by the European Organization for Research and Treatment of Cancer (Brussels, Belgium), and they are considered to be high-quality tools by numerous international organizations and associations working for people with cancer [9, 13]. The survey also included authors' own questions regarding patients' age, height, weight, marital status, place of residence, level of education, use of tobacco, and alcohol consumption. Throughout the survey, participants were provided with instructions on how to fill in the questionnaires.

The EORTC QLQ-C30 questionnaire is made up of 30 questions grouped into nine symptom scales (fatigue, nausea, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties), five functional scales (emotional, physical, role, social, and cognitive), and one global health status scale [9, 13, 14]. The EORTC QLQ-PR25 questionnaire, which is a supplementary module for prostate cancer patients, consists of 25 questions divided into four symptom scales (urinary, incontinence aid, bowel, and hormonal treatment), and two functional scales concerning sexual activity and functioning. Participants answer questions on a four-point scale ('very', 'much', 'little', 'not at all'), except for two questions regarding global health status, where respondents reply on a seven-point scale [9, 13, 14]. In both questionnaires, higher results on the functional scale indicate a higher quality of life in that particular domain. On the other hand, higher scores on symptom scales indicate a worsening of symptoms. A mode of interpretation of results for the purpose of identifying changes in quality of life was proposed by King [15], namely: a difference of five points is not considered significant, a 10-point difference is regarded as clinically significant, while a 20-point difference is considered highly significant.

Statistical analysis. Baseline socio-demographic and clinical characteristics were analyzed using descriptive statistics. The median, lower and upper quartile, and mean and standard deviation were calculated for each symptom and functional scale of the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires, before and after surgery. The analyses were performed using the STATISTICA Stat Soft programme. The Wilcoxon test was used to compare baseline and follow-up results. The level of statistical significance was p<0.05.

RESULTS

Baseline characteristics. The pilot study involved 31 male patients diagnosed with prostate cancer who qualified for radical prostatectomy. Their baseline characteristics are presented in Tables 2 and 3. Table 2 shows characteristics in terms of median value, range, mean, and standard deviation, while Table 3 shows descriptive characteristics in numbers and percentages.

According to these data, certain differences among the study participants may be observed. The level of education was lower than high school among nearly 60% of the group (N=18). The vast majority of participants were married (over 90%, N=29). There was a small difference between the

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Table 2. Baseline characteristics of PCa patients (N=31)

Variable	Mdn	R	x	SD
Age (years)	65.00	54.00-73.00	65.32	4.17
Height (m)	1.73	1.63-1.84	1.73	0.05
Weight (kg)	82.00	67.00-102.00	83.32	9.79
BMI (kg/m²)	26.99	23.74–34.60	27.71	3.04
PSA level (ng/mL)	6.00	2.90-18.00	8.21	4.89

BMI – Body Mass Index; **PSA** – Prostate Specific Antigen; **Mdn** – Median; **R** – Range; $\overline{\mathbf{x}}$ – Mean; **SD** – Standard Deviation

numbers of professionally active (N=15, 48.37%) and inactive (N=16, 51.63) participants. A minority of participants smoked or drank alcohol at the time of the study, N=5 (16.13%) and N=13 (41.94%) respectively. At least one comorbidity was reported among 19 participants (61.29%), the most common of which was cardiovascular disease. Finally, in terms of the pathological stage of the tumour, 17 (54.84%) and 14 (45.16%) participants had pathological T2 and T3 disease, respectively (Tab. 3).

Table 3. Baseline characteristics of PCa patients (N=31)

Variable	N	%
Educational level	.,	,,,
< high school	18	58.06
≥ high school	13	41.94
Marital status	15	41.54
married	29	93.55
not married /single	2	6.45
Current professional status		0.13
active	15	48.37
inactive	16	51.63
Currently smoking	10	31.03
yes	5	16.13
no	27	83.87
Currently drinking alcohol	2,	03.07
yes	13	41.94
no	18	58.06
Comorbidities, any		30.00
yes	19	61.29
no	12	38.71
Gleason score		
6	13	41.94
7	14	45.16
8	4	12.90
Pathological stage of tumor		
pT2a	3	9.68
pT2b	3	9.68
pT2c	11	35.48
pT3a	10	32.26
pT3b	4	12.90
pT3c	0	0.00
Surgery		
open	9	29.03
laparoscopic	22	70.97

Results from EORTC QLQ-C30 questionnaire. In the global health status domain, statistically and clinically significant changes (over -20 points; p<0.001) were observed, indicating severe deterioration in the general quality of life three months postoperatively (-33.87 points; p<0.001).

Statistically and clinically significant differences were also found on the functional scales. The smallest changes between baseline and 3-month follow-up results were observed in the cognitive and physical functioning domains (-20.43 and -27.74 points, respectively (p<0.001), while the greatest differences (over -40 points) were found on the emotional and social functioning scales (-47.31 and -58.60 points, respectively; p<0.001).

Regarding the results from the symptom subscales, where higher scores indicate a worsening of quality of life, the domains which presented the largest deteriorations from baseline to follow-up were the domains of insomnia, dyspnea, and fatigue (+21.51, +37.64, and +40.14 points, respectively; p=0.001 (insomnia), p<0.001 (dyspnea and fatigue)). However, the greatest change among all symptom scales was observed in the financial difficulties domain (+45.16 points; p<0.001), which indicated a serious worsening. The nausea and vomiting, constipation, and diarrhea domains did not present statistically or clinically significant changes (+1.07, -5.38, and +2.15 points, respectively; p>0.05). Change in the loss of appetite domain was observed as statistically and clinically significant (+11.83 points; p=0.003); however, the size effect was small (rc=0.11), indicating that the change was negligible in spite of its technical significance (Tab. 4).

Results from EORTC QLQ-PR25 questionnaire. Statistically significant changes were observed in all domains of the functional and symptom scales of the EORTC QLQ-PR25 questionnaire. The incontinence aid scale results had zero variance in the baseline measurement and were therefore omitted, but it should be noted that the number of participants using incontinence aids was seven (22.58%) at baseline and 31 (100.00%) following radical prostatectomy. However, there was no information available on how many patient had undergone radical prostatectomy with nerve sparing.

The largest differences were observed in the functional domains of sexual activity and sexual functioning (-31.72 and -61.11 points, respectively; p<0.001), indicating a marked deterioration in the sexual quality of life.

Among the symptom scales, the largest changes were found in the urinary symptoms and hormonal treatment-related symptoms domains (+45.83 and +11.11 points, respectively; p<0.001), again presenting a significant clinical worsening in the quality of life. Statistically and clinically significant change was also found on the bowel symptoms scale (+3.49 points; p=0.013); however, as in the case of the appetite loss scale described above, the size effect was small (rc=0.16), indicating that this change is in fact negligible (Tab. 4).

DISCUSSION

Observational or interventional studies focusing on aspects of health-related quality of life bring to the fore patients' expectations and individual needs in relation to cancer treatment and management [9]. Moreover, patient-reported outcomes concerning the severity of symptoms or functional

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Table 4. Quality of life of PCa patients at baseline and 3 months after radical prostatectomy (N=31)

EORTC QLQ-C30		Baseli	ne				3-Month Fo	ollow-Up	
	Mdn	Q ₁ -Q ₃	х	SD	Mdn	Q ₁ -Q ₃	х	SD	p-value (vs. baseline)
Global Health Status	66.67	50.00-83.33	70.16	15.33	41.67	25.00-41.67	36.29	13.18	<0.001*
Functional scales									
Physical functioning	86.67	73.33-93.33	81.29	17.76	60.00	40.00-66.67	53.55	22.87	<0.001*
Role functioning	100.00	66.67-100.00	89.25	16.41	50.00	33.33-66.67	46.24	18.61	<0.001*
Emotional functioning	75.00	66.67-91.67	76.61	13.34	33.33	16.67-41.67	29.30	16.51	<0.001*
Cognitive functioning	100.00	83.33-100.00	89.78	17.57	66.67	66.67-83.33	69.35	17.27	<0.001*
Social functioning	100.00	66.67-100.00	85.48	18.63	33.33	16.67-33.33	26.88	14.71	<0.001*
Symptom scales									
Fatigue	33.33	22.22-33.33	25.81	15.29	15.00	55.56-66.67	65.95	18.36	<0.001*
Nausea and vomiting	0.00	0.00-0.00	1.08	4.16	2.50	0.00-0.00	2.15	5.68	0.317
Pain	16.67	0.00-33.33	17.74	18.73	11.93	16.67-50.00	36.02	22.81	<0.001*
Dyspnea	0.00	0.00-33.33	10.75	18.03	14.00	33.33-66.67	48.39	24.10	<0.001*
Insomnia	33.33	0.00-33.33	22.58	21.75	10.26	33.33-66.67	44.09	15.84	0.001*
Appetite loss	0.00	0.00-0.00	6.45	13.39	5.50	0.00-33.33	18.28	20.80	0.003*
Constipation	0.00	0.00-0.00	9.68	19.61	3.50	0.00-0.00	4.30	11.36	0.107
Diarrhea	0.00	0.00-0.00	3.23	10.02	3.50	0.00-0.00	5.38	12.46	0.414
Financial difficulties	0.00	0.00-33.33	10.75	19.98	15.00	33.33-66.67	55.91	23.39	<0.001*
Symptom scales									
Urinary symptoms	16.67	8.33-33.33	22.58	17.10	66.67	62.50-75.00	68.41	10.69	<0.001*
Bowel symptoms	0.00	0.00-8.33	5.65	10.84	0.00	0.00-16.67	9.14	12.97	0.013*
Hormonal treatment-related symptoms	11.11	5.56-22.22	13.08	8.79	22.22	22.22-27.78	24.19	6.34	<0.001*
Functional scales									
Sexual activity	50.00	33.33-50.00	43.01**	19.61**	0.00	0.00-16.67	11.29**	12.46**	<0.001*
Sexual functioning ^a	70.83	58.33-83.33	69.44**	15.67**	0.00	0.00-14.58	8.33**	8.51**	<0.001*

* N=24; **FORTC QLQ-C30** – European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Items; **FORTC QLQ-PR25** – European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Prostate 25 Items; **Mdn** – Median; \mathbf{Q}_1 – \mathbf{Q}_3 – Lower Quartile-Upper Quartile; $\overline{\mathbf{x}}$ – Mean; **SD** – Standard Deviation; * statistically significant result (Wilcoxon test; p≤0.05); **

difficulties can be subjected to more detailed follow-up assessment, providing more information concerning the impact of different treatment methods [12, 16]. Problems reported by patients (e.g. pain, fatigue, decreases in physical activity) can constitute the basis for further modifications in treatment planning and management (e.g. nursing care, physiotherapy, occupational therapy, nutrition) [17]. Finally, health-related quality of life is also significant in the decision-making processes because the effects on different aspects of the quality of life can be predicted on the basis of previously-conducted systematic reviews, meta-analyses, or randomized controlled trials [12, 13, 16, 17].

The present study is one of the few detailed studies assessing the health-related quality of life among the Polish prostate cancer population following radical prostatectomy. A substantial advantage of the design of the present study is that standardized questionnaires, approved by many international organizations concerned with cancer and its treatment, were used. It should be noted, however, that this was a pilot study performed on a relatively small group of patients, and that the time between surgery and follow-up assessment was relatively short. The discussion of findings can therefore only be indicative of possible directions of changes in quality of life following radical prostatectomy.

The findings of the study indicate severe deteriorations in the quality of life among prostate cancer patients treated with radical prostatectomy. The results of previous studies show that the severest decreases in the quality of life occur in the first months following oncology surgery [9, 18, 19]. The study by Shin et al. indicates that most of the functional and symptom domains of the EORTC QLQ-PR25 questionnaire show significant deterioration at three months post-surgery, e.g. in sexual activity (-13.9 points; p<0.001), sexual functioning (-18.1 points; p<0.001), incontinence aid (+16.9 points; p<0.001), and urinary symptoms (+7.0 points; p<0.001) [18]. Similar findings were reported by Holze et al., who found urinary function and sexual life to be the most adversely affected areas: the urinary symptoms, sexual activity, and sexual functioning domains all worsened significantly (+12.5 points; p<0.001, -15.6 points; p<0.001, and -17.7 points; p<0.001, respectively) [19]. Overall, the studies by Shin et al. [18], Holze et al. [19], and the current study indicate that urinary incontinence and erectile dysfunction are the most common side-effects of radical prostatectomy [6, 8, 9, 20].

Another important finding of the current study is that the quality of life domains associated with psychosocial functioning are more seriously affected than those concerning physical health. It can be concluded therefore that the new life situation in which patients find themselves – experiencing cancer diagnosis, surgery, and hospitalization – strongly affects the state of their mental and social health. This is in agreement with earlier observations by Baba et al., indicating the psychological distress of prostate cancer patients and their need for psychosocial care [21]. Likewise, Kollberg et al. have

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demonstrated a connection between prostate cancer surgery and social well-being by indicating that up to 30% of prostate cancer patients present symptoms of social constraint after radical prostatectomy [22]. Holze et al. also found a worsening of of non-physical quality of life aspects, with significant decreases in the role and social functioning domains three months after surgery (>10 points; p<0.001, EORTC QLQ-C30 questionnaire) [19]. These findings and previously referenced studies suggest that cancer diagnosis and treatment (radical prostatectomy, in this case) significantly affect the psychosocial aspects of the quality of life.

However, in contrast to earlier findings by Shin et al. [19], Holze et al. [20], and Albisinni et al. [23], the results obtained in the current study also show clinically serious deteriorations in the physical aspects of quality of life – specifically on the physical functioning, fatigue, pain, dyspnea, and insomnia scales, which all worsened significantly (i.e. with changes of more than 15 points; p<0.001) three months after surgery. This is at variance with the findings of Holze et al. and Shin et al., which show only clinically insignificant differences three months postoperatively in domains concerning physical health [18,19], whereas Albisinni et al. found that scores for physical functioning and global health status returned to baseline three months following surgery [23]. These differences might be explained by the fact that baseline - follow-up changes in the quality of life domains may be caused by factors not directly associated with cancer.

The results of the present study should be viewed in the light of its limitations, of which the primary limitation is the small number of participants. The second limitation concerns the short time of postoperative observation, only three months. In this connection, the results and practical implications of the present study should be regarded with caution.

CONCLUSIONS

The findings of the present study indicate that health-related quality of life worsens three months after radical prostatectomy across multiple domains: physical, emotional, and sexual, as well as social and economic. It is hoped that these findings will assist healthcare professionals to better understand the changes that occur in the lives of cancer patients, and in selecting more relevant interventions with consideration of the health-related quality of life of the patients. These results could be a starting point for developing interventions to be performed by different groups of healthcare professionals which will contribute to the improvement or maintenance of a satisfactory quality of life for patients, particularly in its psychosocial aspects. Future studies on the current issue with a focus on a longer post-surgical period, and using a larger participant group, are strongly recommended.

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