Medical and social substantiation of the problem of quality of life of patients with prostate cancer

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Introduction. Prostate cancer (PC) is one of the most common cancers among men over 50. Nowadays in Ukraine, the number of new cases of PC tends to increase according to statistics.

Objectives. The aim of the study is to identify the main problems in the life quality of patients with PC (C61) to optimize medical care for them.

Methods. The main aspects of the quality of life of PC patients are studied by means of EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires.

Results. In Ukraine, as of the pre-war period (November 2021 – February 2022), the quality of life of patients with PC amounted to 52.31 on a 100-point scale. The worst indicators within the functional scale QLQ-C30 belonged to the subscale “Role functioning” (65.44). According to the QLQ-C30 symptoms scale, the highest score among the complaints of Ukrainian patients is fatigue (48.58). Given the results of our research on the QLQ-PR25 symptom scale, patients with PC were the most worried about “Urinary symptoms”, with a score of 38.54 out of 100. According to the functional scale QLQ-PR25, the worst indicators were for “Sexual activity”, which is equal to 32.22 points on a 100-point scale.

Conclusions. It is important to create socio-psychological support for patients with PC and their families, which will include the development and implementation of standardized psychological care at all stages of diagnosis, treatment and rehabilitation.

Keywords: Oncology, prostate cancer, quality of life, socio-psychological support.
**Introduction**

Prostate cancer (PC) is a malignant neoplasm that develops from the epithelium of the prostate. This disease is one of the most common cancers among men, as it ranked 4th after cancer of the trachea, bronchi, lungs, colon and rectum and stomach cancer in 2019 [1, 2]. This type of cancer is most common for men over the age of 50 [2, 3].

Nowadays in Ukraine, the number of new cases of PC among the male population tends to increase. In particular, according to the National Cancer Registry, 8,178 cases were detected in 2019 [4].

The death rate due to PC is 41 cases per 100 thousand people in Ukraine. In the world, this figure amounts to 18.7 per 100 thousand [3]. This statistic is primarily due to the fact that men rarely turn to a specialist since we do not have a culture of preventive examinations by a urologist.

Today in Ukraine, metastatic disease is found in 21% of newly diagnosed patients. In the US, this figure amounts to only 5%. All of this causes high mortality during the first year after diagnosis – 16.5% according to the Cancer Registry [3].

Cancer survival, functional indicators and quality of life are the most important results for a patient with PC. Patients with newly diagnosed PC at an early stage are faced with a difficult choice of different treatment options and they must take both goals, survival and optimization of the quality of life, into account [5–7].

**Materials and Methods**

The sociological study was performed by surveying 408 patients at the stage of their inpatient treatment according to a unified study protocol, which included the use of a comprehensive questionnaire to determine the quality of life in oncology EORTC QLQ-C30 and a questionnaire to determine the quality of life of patients with PC QLQ-PR25. Permission to use EORTC Quality of Life Group questionnaires was obtained in November 2021.

EORTC QLQ-C30 is a questionnaire of the European Organization for Research and Treatment of Cancer, developed by the EORTC Quality of Life Study Group [8]. The current version consists of 30 questions and includes 5 functional scales: physical functioning (PF2), role functioning (RF2), emotional functioning (EF), cognitive functioning (CF) and social functioning (SF). QLQ-C30, symptom scales include fatigue (FA), insomnia (SL), diarrhea (DI), nausea and vomiting (NV), appetite loss (AP), dyspnea (DY), pain (PA), constipation (CO) and financial difficulties (FI).

The study was conducted in oncological institutions in nine regions of Ukraine: Chernihiv, Zaporizhia, Dnipropetrovsk, Kyiv, Poltava, Khmelnytskyi, Ivano-Frankivsk, Zakarpattia and Lviv. Primary data were collected from November 2021 to February 2022. All participants gave written consent to participate in the study.

A randomized study was conducted with patient stratification by the stage of the disease. The distribution of patients by the stage of the disease is as follows: I stage – 0.2%, II stage – 37.0%, III stage – 18.6%, IV stage – 31.9%, the stage was not determined in 12.3% of patients. The distribution data are identical to the average data in Ukraine.

The more frequent concomitant pathologies in patients with PC were cardiovascular diseases (arterial hypertension, ischemic heart disease, postinfarct cardioctherosclerosis), which accounted for 84% of patients; urinary system diseases (uro lithiasis, chronic pyelonephritis, kidney cysts) – 32% of patients; respiratory diseases (chronic obstructive pulmonary disease) – 7% of patients and endocrine diseases (type II diabetes) – 2% of patients.

24.9% of patients received surgical treatment (radical prostatectomy), radiation therapy – 23.4% of patients, hormonal therapy – 13.4% of patients, combined treatment – 21.5% of patients, and 16.8% of patients did not receive special treatment.

Calculations were performed according to the EORTC QLQ-C30 Scoring Manual [8] and QLQ-PR25 [5]. The analysis of three main indicators was performed: functional scale (FS), symptom scale (SS) and quality of life (QoL). First of all, the average score (Raw Score – RS) for each indicator was estimated, which is presented in the form of M±SD.

Since the structure of the questionnaire enables the questions to have a 4 or 7-point scale, the developers proposed a unified approach by using a 100-point scale for each of the parameters. Thus, the value of the functional scale (FS) per 100 points was calculated by the following formula:

\[ FS = (1-(RS-1)/range)*100, \]

where RS is the average score of the scale, range is the range of the scale, which is determined by the difference between the possible maximum and minimum values of the scale.
Meanwhile, the symptom scale (SS) and quality of life (QoL) for 100 points were calculated by the following formula:

\[ SS = \left(\frac{RS-1}{\text{range}}\right) \times 100, \]

where RS is the average score of the scale, range is the range of the scale, which is determined by the difference between the possible maximum and minimum values of the scale.

Obtained results were interpreted according to the traditional approach: a high level of functional scale (FS) indicated a high (healthy) level of functioning on this indicator. Similarly, a high level of quality-of-life scale (QoL) indicated a high quality of life, but a high level of the symptom scale (SS) indicated a high level of this problem or symptom existence.

For scales consisting of 2 or more questions, Cronbach’s alpha was calculated as an indicator of the consistency of the scale.

**Results**

According to the results obtained, the quality of life of GLOBAL HEALTH STATUS (GHS) / QoL of patients with PC amounted to 52.31 points on a 100-point scale. It should be noted that the answers of the respondents were of the same type, as indicated by the very high consistency, which was determined by the method of Cronbach and constituted 0.93.

According to the questionnaire within the functional scale QLQ-C30, among other subscales, the worst indicators fell on the subscale “Role functioning”, which amounted to 65.44 points on a 100-point scale (Table 1), and the average score was 2.04±0.88. This section of the scale includes questions about the patient’s limitations in the performance of their work and daily activities, as well as limitations on hobbies or other leisure activities.

**Table 1. Results of the QLQ-C30 functional scale survey of PC patients**

<table>
<thead>
<tr>
<th>Scale items</th>
<th>Directory code</th>
<th>Score on a 100-point scale</th>
<th>&amp; Cronbach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role functioning</td>
<td>RF2</td>
<td>65.44</td>
<td>0.71</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>EF</td>
<td>69.70</td>
<td>0.85</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>PF2</td>
<td>70.31</td>
<td>0.82</td>
</tr>
<tr>
<td>Social functioning</td>
<td>SF</td>
<td>74.12</td>
<td>0.75</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>CF</td>
<td>77.11</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Compared to the previous points, the score in the subscale “Emotional functioning” is slightly higher and amounts to 69.70 out of 100. This subscale combines questions about the stress, anxiety, irritation, and depression of a patient with PC.

The result of the subscale “Physical functioning” was slightly better, its score was 70.31 on a 100-point scale. According to the questionnaire, patients found it harder to do strenuous physical work, walk for a long/short time, carry heavy suitcases; some patients stayed in bed or chairs during the day and/or needed help while eating, dressing, performing hygienic procedures, which in turn affected the patient’s self-esteem, their emotional background.

The “Social functioning” indicator amounts to 74.12 points on a 100-point scale. This section of the scale includes questions about limitations and discomforts in family life and communication with people related to the patient's physical condition or treatment.

The best indicators in the functional scale QLQ-C30 belonged to “Cognitive functioning”, which had a score of 77.11 on the 100-point scale. This indicates that most patients did not have difficulty concentrating and remembering, for example, when reading a newspaper or watching a TV show.

In general, Cronbach’s alpha on the QLQ-C30 functional scale of patients with PC ranged from 0.71 to 0.85, indicating sufficient and high consistency of patient responses.

The worst results of the QLQ-C30 symptom scale belonged to the subscale "Fatigue", its average score is 2.46±0.87. The score on a 100-point scale for this item amounted to 48.58 (Figure 1). The presence of fatigue significantly affects the quality of life, this symptom often worries patients with malignant neoplasms and is reflected in their physical and
psychological state. Both the disease and the therapy affect the quality of life in all its dimensions, in particular the manifestation of frequent patient fatigue.

According to the results of the survey, financial difficulties are less difficult for patients with PC, which was expressed in 47.30 points on a 100-point scale. In general, when interviewing Ukrainian patients with various types of cancer, this figure is quite high and is the leading subscale of the QLQ-C30 symptom scale.

Pain ranks third in the results of the survey on the QLQ-C30 symptom scale of patients with PC. It amounted to 42.48 points on a 100-point scale. If the tumor grows outside the prostate capsule, then the pain is localized in the perineum and the pubic area or above the pubic bone. Pain in the back (especially frequent in the lower back), legs, and chest may appear as the first sign characteristic of metastases, while the intensity of pain in patients varies. There is a close relationship between the patient's subjective assessment of the quality of life and pain, which greatly complicates daily activities. This indicates the need for continuous monitoring and relief of pain directly related to cancer and treatment methods.

According to the data obtained, “Insomnia” amounted to 37.91 points on a 100-point scale. Frequent nocturnal urination is one of the possible symptoms of PC. According to the results of the survey, patients with PC are less worried about dyspnea, which was expressed in 32.60 points on a 100-point scale.

The “Appetite loss” indicator is almost commensurate with the previous paragraph. It scored 32.27 points on a 100-point scale. Cancer patients may develop an aversion to food and an inversion of taste. As a result, eating disorders significantly increase the risk of complications of chemotherapy and radiation therapy, as well as postoperative complications.

According to the obtained data, “Constipation” received 27.44 points on a 100-point scale. Patients were less concerned about diarrhea, and the QLQ-C30 symptom score was 25.53.

Patients with PC were the least worried according to the QLQ-C30 questionnaire, nausea and vomiting symptoms scale. The score for this indicator was 17.46 on a 100-point scale.

Under Cronbach's alpha value in QLQ-C30, the scale of symptoms ranged from 0.76 to 0.89, indicating sufficient and high consistency of patient responses.

The quality of the patient’s life with PC depends on the stage of cancer treatment, type of therapy or significant deterioration in the last stage of the disease.

The EORTC QLQ-PR25 module for PC has been available since mid-2006. The QLQ-PR25 questionnaire is an additional questionnaire containing four scales of symptoms that are of major interest for assessing the quality of life of patients with PC. These are symptoms related to defecation, urination, treatment and sexuality [6, 9].
The worst indicator and the highest score of the QLQ-PR25 symptom scale belonged to the subscale “Urinary symptoms” and amounted to 38.54 out of 100 (Figure 2), its average score was 2.16±0.94. This subscale included questions about the frequency of urination during the day and night, and pain when urinating. Patients were asked whether urological problems limited their daily activities or whether it was difficult for them to leave the house because they felt the need to be near the toilet.

Slightly better indicators we observed for “Incontinence aid”, the score was 34.90 on a 100-point scale. Up to this point, the scales asked if patients had had problems with the urinal because of wearing it.

Patients were less concerned about hot flashes, painful or enlarged nipples or breasts, swollen legs or ankles, and weight loss problems. “Hormonal treatment-related symptoms” had a score of 26.83 on a 100-point scale. At this point, patients were asked if they felt less courageous because of this disease or treatment.

According to the results obtained, the best indicators were observed in the subscale “Bowel symptoms”, its score was 23.25 out of 100 possible. This subscale includes questions about bloating, blood in the stool, involuntary bowel movements, and whether or not bowel problems have limited the patient’s daily activities.

Overall, Cronbach’s alpha score on the QLQ-PR25 symptom scale ranged from 0.78 to 0.91, indicating a sufficient and very consistent patient response. Only in the subscale “Hormonal treatment-related symptoms”, it was equal to 0.61, which corresponds to the questionable consistency of patient responses.

The QLQ-PR25 functional scale of patients with PC includes two subscales: “Sexual Activity” and “Sexual Function”. The lowest results with a score of 32.22 points on a 100-point scale (Table 2) and an average score of 3.03±0.91 were observed for the subscale “Sexual Activity”. This section of the QLQ-PR25 functional scale includes questions about whether the patient was interested in sex and how sexually active the patient was.

<table>
<thead>
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<th>Directory code</th>
<th>Score on a 100-point scale</th>
<th>&amp; Cronbach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual Activity</td>
<td>SAC</td>
<td>32.22</td>
<td>0.82</td>
</tr>
<tr>
<td>Sexual Function</td>
<td>SFU</td>
<td>52.78</td>
<td>0.88</td>
</tr>
</tbody>
</table>

The highest indicator is characterized by the subscale “Sexual Function”. It amounted to 52.78 points on a 100-point scale. This section includes questions about difficulties, problems with erection and ejaculation, as well as whether the patient felt uncomfortable about sexual intimacy and in general how pleasant it was for him to have sex.
Cronbach’s alpha on the QLQ-PR25 functional scale ranged from 0.82 to 0.88, indicating high consistency in patient responses.

Discussion
Global Health Status (GHS) is the value of self-assessment of the patient’s quality of life. The GHS value of Ukrainian patients suffering from PC corresponds to 52.31 points on a 100-point scale, which is lower than the GHS of European and American patients. In 2006, Arredondo and co-authors described GHS at 76.3 points, which changed to 74.1 points on average two years after radical extrapubic prostatectomy in 854 American patients [9]. In general, younger patients may subjectively experience a greater decline in the quality of life due to better general health. Peter Bach and co-authors describe GHS as starting at 73.8 points before prostatectomy and ending at 69.4 points after prostatectomy in German patients [10].

According to our data, among other subscales, the worst indicators within the functional scale QLQ-C30 were attributed to the subscale “Role functioning”, which amounted to 63.44 points on a 100-point scale, which is much lower than for German patients (91.4–92.2) [10].

The results of the survey obtained by us on the scale of symptoms QLQ-C30 reflect the highest score among the complaints of fatigue (48.58). This figure is much higher than the value of 27.6 obtained by French colleagues. What we and our French colleagues have in common is that it is the Fatigue subscale that, according to its results, tops the list of the QLQ-C30 symptom scale [11].

According to the results of our studies, patients were most concerned about the QLQ-PR25 “Urinary Symptoms” with a score of 38.54 on a 100-point scale, which is higher than the European patient score of 17–21.1 [11, 12] and patients with non-metastatic castration-resistant prostate cancer (24) [13]. The worst performance on the functional scale QLQ-PR25 of patients with PC was observed for the subscale “Sexual Activity”, which had 32.22 points on a 100-point scale, which is lower than that in the German patients, where the score is 59.0 [12].

According to the results obtained by us, patients were least concerned about the functional scale QLQ-PR25 “Sexual Function”, which is consistent with the data obtained by Martin H. Umbehr, Lucas M. Bachmann, Cedric Poyet, Peter Hammerer, Johann Steurer, Milo A. Puhan and Anja Frei, but the figures are different; for Ukrainian patients, the score is 52.78, for foreigners – 79.5 [12]. According to the QLQ-PR25 symptoms scale, Ukrainian patients had the least problems with “Bowel symptoms” (23.25), just as European patients, but with a lower rate of 4.5 [12]. According to the QLQ-C30 symptom scale, nausea and vomiting were the lowest (17.46), like in German and French patients, but again with a lower score of 1–3 [10–12]. According to the results of the functional scale QLQ-C30, the patients had the highest indicators in the subscale “Cognitive functioning”, which was 77.11 on a 100-point scale, which is consistent with the figure obtained by French researchers 78.0 [11].

Data on the effects and side effects of different treatments on quality of life, outcomes reported by patients and appropriately assessed relevant aspects of quality of life, are important to facilitate physicians’ decisions about treatment choices given changes in patient quality of life over time.

The analysis of the main aspects of the patients; quality of life with PC allows us to draw the following conclusions:

1. In Ukraine, as of the pre-war period (November 2021 – February 2022), the quality of life of PC patients amounted to 52.31 points on a 100-point scale. This figure is lower than in European countries, where it amounted to 69.4–76.3 points. Ukrainian patients find “Role functioning” (65.44), “Emotional functioning” (69.70); “Fatigue” (48.58), “Financial difficulties” (47.30); “Urinary Symptoms” (38.54), and “Sexual activity” (32.22) the most disturbing.
2. Given the low quality of life, it is important to create socio-psychological support for patients with PC and their families, which will include the development and implementation of standardized psychological care at all stages of diagnosis, treatment and rehabilitation; and mental health care in all medical facilities that provide treatment to patients with PC. It is also important to implement a multidisciplinary approach that will involve family physicians, oncology specialists and psychologists.
3. In developing comprehensive programs/strategies for providing cancer care to the population of Ukraine, the ways of supporting cancer patients, except for physicians, by all members of society should also be taken into account. This leads to the development of ways to raise awareness of the population (including family members and staff) about the need for socio-psychological support for patients treated for cancer.
References

5. EORTC quality of life. Prostate. Questionnaire. Available at: https://qol.eortc.org/questionnaire/qlq-pr25/