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REVIEW ARTICLE

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EORTC QLQ-C30 and EORTC QLQ-PR25 — tools for assessing the quality of life of men suffering from prostate cancer

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ABSTRACT

Introduction and objective. The assessment of the quality of life in cancer patients has become an indispensable element of clinical trials of applications of new treatments and surgical variants and springs from a desire to achieve therapeutic success in various aspects of patients' lives. This article aims to present and describe the EORTC QLQ-C30 questionnaire, used for assessing the quality of life, and the complementary EORTC QLQ-PR25 questionnaire, which is used in cases of prostate cancer.

Brief description of the current state of knowledge. Cancer diagnoses lead to psychological, physical, emotional, and economic burdens which can have a great effect on the quality of life. The cancer population is increasing from year to year, creating many challenges for healthcare systems. In Poland, prostate cancer accounts for 19.6% of all diagnosed cancers in the male population, thus presenting a growing trend. The multiplicity of possible treatment methods and increasing interest in the quality-of-life assessment means that proper choice of treatment depends in part on the results of clinical trials which evaluate the quality of life among patients being treated by specific methods. For such assessment, the European Organization for Research and Treatment of Cancer has developed a questionnaire assessing the impact of disease on different aspects of patients' lives, as well as supplementary questionnaires for particular types of cancer.

Conclusion. The application of standardized questionnaires for the assessment of the quality of life among cancer patients is becoming an integral part of clinical trials, which, along with other factors, may help in the selection of the most appropriate treatment methods.

Key words: quality of life, prostate cancer, EORTC QLQ-C30, EORTC QLQ-PR25

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Introduction

It is difficult to clearly define the concept of quality of life because the quality of life is a strongly subjective feeling composed of individual needs, expectations, and values. According to the definition of the World Health Organization (WHO), quality of life is defined as a subjective assessment by an individual of their life situation, a system of values, goals, expectations, and interests in the context of the culture in which that individual lives [1, 2].

Interest in the quality of life in medical sciences and health sciences emerged in the 1970s and 1980s, when,

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alongside the development of medical treatments, patient dissatisfaction with treatments was often reported, despite their promising prognoses. Thus, attention was drawn to the need to achieve satisfactory treatment results in all spheres of the patient's life [1, 2]. Assessment of the quality of life allows understanding of the patient's subjective feelings about the adopted treatment strategy, thereby involving him or her more deeply in the process of therapy [2, 3].

Quality of life in cancer cases

An assessment of the quality of life has become one of the important elements of oncological care, as it is used in determining the impact of the disease and treatment on various spheres of the patient's life. It is an extremely important variable that represents the patient's biopsychosocial state [4, 5]. Therefore, this assessment has become one of the end goals of clinical trials evaluating new treatment options and surgical techniques. Moreover, the inclusion of quality-of-life assessment in studies of the cancer-patient population allows for the planning and development of health recovery or maintenance programs. A cancer diagnosis is associated with significant physical, emotional, social, and economic burdens. Patients adapting to cancer face many problems, which are reflected in their cognitive, emotional, and social functioning [6–8].

Prostate cancer

Prostate cancer is the most frequently diagnosed malignant neoplasm among men in Poland and accounts for 19.6% of all diagnosed cases [9]. Over the last decades, its detection rate has increased several times, which indicates that in the coming years prostate cancer will be the most common malignant neoplasm among men in Poland [9, 10]. Ethnic origin, advanced age, and genetic predisposition are confirmed factors that increase the risk of prostate cancer. On the other hand, unconfirmed factors influencing the risk of developing the disease are lifestyle (diet, level of physical activity, use of stimulants) and long-term exposure to UV radiation [11–13]. Currently, the main methods of treating prostate cancer are watchful waiting, active surveillance, radical prostatectomy, radiotherapy, brachytherapy, chemotherapy, and pharmacotherapy. Cryotherapy and high-intensity focused ultrasound effectiveness are still under researchers and clinicians' consideration [12]. Scientific research and expert debates on prostate cancer treatment methods indicate that achieving therapeutic success often requires some combination of the above-mentioned treatment methods [11, 12].

Moreover, an important aspect of postoperative care is the treatment of complications following prostate cancer treatment. In the case of radical prostatectomy, the most common complications are urinary incontinence and erectile dysfunction. Radical radiotherapy complications include persistent diarrhea, rectal bleeding, and micturition disorders (e.g. urinary retention and incontinence). In turn, complications after hormone therapy focus on sexual functioning, hot flushes, increased risk of fractures, and psychological side effects (e.g. anxiety, depression, chronic fatigue, and cognitive impairment) [12].To address these problems, pharmacotherapy, physiotherapy, and psychotherapy treatments are employed, among others [14].

Aim of the study

This study aims to present and describe the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires, which assess the quality of life of cancer patients, including prostate cancer.

EORTC and development of the EORTC QLQ-C30 questionnaire

The European Organization for Research and Treatment of Cancer (EORTC) was founded in 1962 in Brussels as an international non-profit organization. Its goal is to lead, develop, coordinate and encourage research in the field of cancer. The EORTC develops and supports research in interdisciplinary teams consisting of doctors, nurses, physiotherapists, and researchers in the field of basic sciences. The conducted and supported research projects mainly consist of randomized, multicenter clinical trials conducted on large populations of patients suffering from cancer [15]. In 1980, the EORTC established the Quality of Life Group, which in 1986 started a research project related to the development of a tool to assess the quality of life of participants in clinical trials in many aspects. This led to the development of the current version of the EORTC QLQ-C30 (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30), which is used to assess the quality of life in all types of cancer. The first version of the questionnaire was created in 1987 as the EORTC QLQ-C36 and contained 36 items, several of which, as it turned out, did not provide clear and specific results. The second version of the questionnaire, containing 30 questions, i.e. the EORTC QLQ-C30 version 1.0, was more commonly employed after its use in studies conducted by Aaronson et al. on a group of lung cancer patients in 13 countries [16]. The next version was the EORTC QLQ-C30 (+3) questionnaire, which recom-

mended additional questions related to the functioning of patients in society and general health. However, this was a transitional version, because, in 1997, a study by Person et al. using version 2.0 with 30 items was carried out, in which a higher internal consistency was achieved on the scale of the functioning of patients in society and the scale of general health was separated from the scale of physical function [17]. The next version of the tool, i.e. the EORTC QLQ-C30 version 3.0 questionnaire, differs from the previous one in the scoring of some questions and the content of one of the questions. This version has been tested in the population of patients with head and neck cancer in studies by Bjordal et al. and is the most current and up-to-date version, used in numerous research studies on the quality of life of cancer patients [18].

An extremely important element in the development of the EORTC QLQ C30 version 3.0 questionnaire is the development by the Quality of Life Group of tools supplementing the basic questionnaire. Specifically, in the 1990s, modules were developed to supplement the basic questionnaire with questions about specific types of cancer, i.e. specific symptoms related to cancer, the side effects of the treatment, and additional aspects of quality of life, related to the disease or treatment [19]. The first of the newly developed modules concerned breast cancer (EORTC QLQ-BR23), head and neck cancer (EORTC QLQ-H & N35), lung cancer (EORTC QLQ-LC13), esophageal cancer (EORTC QLQ-OES24), and ovarian cancer (EORTC QLQ-OV24). There are now over 40 currently validated complementary modules, as well as those at various stages of clinical trials [14].

The EORTC-QLQ-C30 and EORTC-PR25 scales were used by Shin et al. for assessing the effectiveness of various surgical modalities (e.g. open, laparoscopic, and robotic radical prostatectomy) in the prostate cancer population. Results obtained from using EORTC scales showed similar quality of life level 12 months postoperatively [20]. These questionnaires also assessed the effectiveness of immediate versus delayed androgen deprivation therapy in patients suffering from asymptomatic, non-curable prostate cancer over 5 years. The quality-of-life results indicated that immediate androgen-deprivation therapy was associated with early harm in hormone-treatment-related symptoms but had no other effect on global functioning and the quality of life. The evidence from the abovementioned studies can be used to help decision-making about different treatment modalities for the prostate cancer population [21].

EORTC QLQ-C30 version 3.0

The EORTC QLQ-C30 version 3.0 questionnaire is a tool for examining the quality of life of cancer patients in general without taking into account the type, stage, and location of the neoplasm. The questionnaire consists of 30 questions which are divided into 3 main parts:

1. Global health status — questions 29, 30;
2. Functional scales:
   - 2.1. Physical functioning, PF2 — questions 1–5;
   - 2.2. Role functioning, RF2 — questions 6, 7;
   - 2.3. Emotional functioning, EF — questions 21–24;
   - 2.4. Cognitive functioning, CF — questions 20, 25;
   - 2.5. Social functioning, SF — questions 26, 27;
3. Symptom scales:
   - 3.1. Fatigue, FA — questions 10, 12, 18;
   - 3.2. Nausea and vomiting, NV — questions 14, 15;
   - 3.3. Pain, PA — questions 9, 19;
   - 3.4. Dyspnea, DY — question 8;
   - 3.5. Insomnia, SL — question 11;
   - 3.6. Appetite loss, AP — question 13;
   - 3.7. Constipation, CO — question 16;
   - 3.8. Diarrhea, DI — question 17;
   - 3.9. Financial difficulties, FI — question 28.

The questions are answered by respondents on a 4-point scale (1 — not at all, 2 — little, 3 — much, 4 — very much) assessing the intensity of the analyzed parameter. The only exceptions are the last two questions of the questionnaire, which concern a general assessment of health, where a 7-point scale is used [18, 22].

EORTC QLQ-PR25

The EORTC QLQ-PR25 questionnaire is a supplement to the EORTC QLQ-C30 questionnaire and is designed to assess symptoms related to prostate cancer, its treatment, and aspects of life related to this type of cancer. It consists of 25 questions, to which the respondents answer: "not at all," "little," "much," or "very." The questions included in the questionnaire are grouped into symptom scales and functional scales [23–25].

1. Symptom scales:
   - 1.1. Urinary symptoms, URI — questions 1–7, 9;
   - 1.2. Incontinence aid, AID — question 8;
   - 1.3. Bowel symptoms, BOW — questions 10–13;
   - 1.4. Hormonal treatment-related symptoms, HTR — questions 14–19;
2. Functional Scale:
   - 2.1. Sexual activity, SAC — questions 20, 21;
   - 2.2. Sexual functioning, SFU — questions 22-25.

Scoring

A statistical compilation of the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires should be carried out strictly according to the guidelines described in the electronic manual, which the EORTC provides by email at the same time as the permission to use the tools

themselves. First, a Raw Score (RS) is computed for each of the scales, and then the ratio is linearly transformed to fall on a scale from 0 to 100. In the EORTC QLQ-C30 questionnaire, obtaining a higher score for the functional scales and the general health scale indicates a higher quality of life while the higher the score on the symptomatic scales, the greater the severity of symptoms. For the EORTC QLQ-PR25 questionnaire, a higher score on the functional scales means a higher level of functioning, but on the symptomatic scales, a higher score means a greater severity of symptoms [26, 27]. In order to assess changes in patients' quality of life (e.g., before and after treatment), the recommendations for interpretation of the results that King proposes in his research can be used [28]. They propose that a difference of 10 or more on the 0–100-point scale is considered as a clinically significant difference and that a difference above 20 points is treated as particularly significant, while a 5-point difference should be regarded as only a possible direction of change, i.e. improvement or deterioration [28]. Full English and Polish versions of the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires are included in the supplementary material (appendix 1 and 2).

Advantages and limitations of the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires

EORTC QLQ questionnaires are widely used in research on the quality of life in cases of neoplastic disease [29–31]. This enables their continuous development, research on their parameters in large groups, and the creation of various language versions, which facilitates their dissemination [32–34]. Studies validating both questionnaires in the population of Polish patients with prostate cancer indicate their reliability in terms of basic psychometric properties. Cronbach's alpha coefficient for both questionnaires ranges from 0.849 to 0.908 [24, 25]. Access to the questionnaires, also in the Polish language, is free, although it requires the permission of the European Organization for Research and Treatment of Cancer. Permission may be obtained by simply completing the application form, available on the organization's website (https://qol.eortc.org/questionnaire/eortc-qlq-c30/) under the "Request questionnaire" tab. Nevertheless, there are some limitations and difficulties in using these questionnaires. While both are available in Polish, the instructions for their use along with the scoring system are in English only. The scoring system, with its calculation of the raw score and its linear transformation, may prove difficult, especially for less experienced or student research teams [33–35].

Summary

Currently, there are many methods and means used in the treatment of neoplasms, including prostate cancer, and therefore their selection is a complex process and should be based on the knowledge and experience of medical personnel, as well as subjective feelings of patients. Quality-of-life studies should, therefore, be used as a tool for describing and predicting treatment outcomes in the cancer population. The use of standardized questionnaires in scientific research, carrying out calculations in accordance with the recommendations, and, obviously, conducting research in accordance with the highest methodological standards, contributes to the creation of high-quality studies that can often constitute an argument in favor of choosing a particular treatment method.

Conflict of interest

The authors have declared no conflicts of interest.

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Appendix 1. Questionnaire EORTC QLQ-C30 (version 3.0.)

Please answer all of the questions yourself by inserting an X the response that best applies to you.The information that you provide will remain strictly confidential.

1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?

Not at all	A little	Quite a bit	Very much

2. Do you have any trouble taking a long walk?

Not at all	A little	Quite a bit	Very much

3. Do you have any trouble taking a short walk outside of the house?

Not at all	A little	Quite a bit	Very much

4. Do you need to stay in bed or a chair during the day?

Not at all	A little	Quite a bit	Very much

5. Do you need help with eating, dressing, washing yourself or using the toilet?

Not at all	A little	Quite a bit	Very much

During the past week:

6. Were you limited in doing either your work or other daily activities?

Not at all	A little	Quite a bit	Very much

7. Were you limited in pursuing your hobbies or other leisure time activities?

Not at all	A little	Quite a bit	Very much

8. Were you short of breath?

Not at all	A little	Quite a bit	Very much

9. Have you had pain?

Not at all	A little	Quite a bit	Very much

10. Did you need to rest?

Not at all	A little	Quite a bit	Very much

11. Have you had trouble sleeping?

Not at all	A little	Quite a bit	Very much

12. Have you felt weak?

Not at all	A little	Quite a bit	Very much

13. Have you lacked appetite?

Not at all	A little	Quite a bit	Very much

14. Have you felt nauseated?

Not at all	A little	Quite a bit	Very much

15. Have you vomited?

Not at all	A little	Quite a bit	Very much

16. Have you been constipated?

Not at all	A little	Quite a bit	Very much

During the past week:

17. Have you had diarrhea?

Not at all	A little	Quite a bit	Very much

18. Were you tired?

Not at all	A little	Quite a bit	Very much

19. Did pain interfere with your daily activities?

Not at all	A little	Quite a bit	Very much

20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?

Not at all	A little	Quite a bit	Very much

21. Did you feel tense?

Not at all	A little	Quite a bit	Very much

22. Did you worry?

Not at all	A little	Quite a bit	Very much

23. Did you feel irritable?

Not at all	A little	Quite a bit	Very much

24. Did you feel depressed?

Not at all	A little	Quite a bit	Very much

25. Have you had difficulty remembering things?

Not at all	A little	Quite a bit	Very much

26. Has your physical condition or medical treatment interfered with your family life?

Not at all	A little	Quite a bit	Very much

27. Has your physical condition or medical treatment interfered with your social activities?

Not at all	A little	Quite a bit	Very much

28. Has your physical condition or medical treatment caused you financial difficulties?

Not at all	A little	Quite a bit	Very much

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7
very poor excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7
very poor excellent

Appendix 2. Questionnaire EORTC QLQ — PR25

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by inserting an X the response that best applies to you.

During the past week:

1. Have you had to urinate frequently during the day?

Not at all	A little	Quite a bit	Very much

2. Have you had to urinate frequently at night?

Not at all	A little	Quite a bit	Very much

3. When you felt the urge to pass urine, did you have to hurry to get to the toilet?

Not at all	A little	Quite a bit	Very much

4. Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?

Not at all	A little	Quite a bit	Very much

5. Have you had difficulty going out of the house because you needed to be close to a toilet?

Not at all	A little	Quite a bit	Very much

6. Have you had any unintentional release (leakage) of urine?

Not at all	A little	Quite a bit	Very much

7. Did you have pain when you urinated?

Not at all	A little	Quite a bit	Very much

Answer this question only if you wear an incontinence aid:

8. Has wearing an incontinence aid been a problem for you?

Not at all	A little	Quite a bit	Very much

9. Have your daily activities been limited by your urinary problems?

Not at all	A little	Quite a bit	Very much

10. Have your daily activities been limited by your bowel problems?

Not at all	A little	Quite a bit	Very much

11. Have you had any unintentional release (leakage) of stools?

Not at all	A little	Quite a bit	Very much

12. Have you had blood in your stools?

Not at all	A little	Quite a bit	Very much

13. Did you have a bloated feeling in your abdomen?

Not at all	A little	Quite a bit	Very much

14. Did you have hot flushes?

Not at all	A little	Quite a bit	Very much

15. Have you had sore or enlarged nipples or breasts?

Not at all	A little	Quite a bit	Very much

16. Have you had swelling in your legs or ankles?

Not at all	A little	Quite a bit	Very much

During the last 4 weeks:

17. Has weight loss been a problem for you?

Not at all	A little	Quite a bit	Very much

18. Has weight gain been a problem for you?

Not at all	A little	Quite a bit	Very much

19. Have you felt less masculine as a result of your illness or treatment?

Not at all	A little	Quite a bit	Very much

20. To what extent were you interested in sex?

Not at all	A little	Quite a bit	Very much

21. To what extent were you sexually active (with or without intercourse)?

Not at all	A little	Quite a bit	Very much

Please answer the next four questions only if you have been sexually active over the last 4 weeks:

22. To what extent was sex enjoyable for you?

Not at all	A little	Quite a bit	Very much

23. Did you have difficulty getting or maintaining an erection?

Not at all	A little	Quite a bit	Very much

24. Did you have ejaculation problems (eg. dry ejaculation)?

Not at all	A little	Quite a bit	Very much

25. Have you felt uncomfortable about being sexually intimate?

Not at all	A little	Quite a bit	Very much