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CAVIPRES questionnaire as a measurement of quality of life in patients with prostate cancer in Spain: Daily clinical practice application

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ABSTRACT

Introduction: Prostate cancer (PC) is the most frequent tumor in elderly patients. Although it is not directly involved in death, PC entails an important losts in patient's quality of life. There are several questionnaires adapted to Spanish in order to measure the health-related quality of life (HRQoL) in PC patients.

Objectives: To describe the content and feasibility of the Spanish CAVIPRES questionnaire both in its short version to the clinical daily practice and also in the extended version to be used in the investigational protocols.

Materials and methods: A detailed review of the different quality of life-related aspects of PC patients gathered in the questionnaire and a cross-comparison with other adapted HRQoL available has been performed.

Results: The HRQoL CAVIPRES questionnaire gathers information regarding social and partner support, psychological conditions of the patients, and also life expectancies against disease outcome together with classical symptomatic parameters such as other available and adapted questionnaires.

Conclusion: The CAVIPRES questionnaire in its short version is adequate, feasible, valid, reliable and sensitive to change in the measurement of HRQoL in PC patients. The extended version is valid to be used in clinical research of PC patients. Both versions have been donated by Abbott to the Spanish Association of Urology (AEU) and are available at AEU web site (www.eau.es).

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Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata como medida de la calidad de vida de los pacientes con cáncer de próstata en España: aplicación a la actividad diaria

Palabras clave:
Calidad de vida
Cáncer de próstata
Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata
Cuestionario
Descripción

RESUMEN

Introducción: El cáncer de próstata (CP) supone el tumor más frecuente en los varones ancianos. A pesar de no ser responsable directo del fallecimiento, implica una merma importante en la calidad de vida de los pacientes. Diversos cuestionarios han sido adaptados al castellano para medir la calidad de vida relacionada con la salud (CVRS) de los pacientes con CP.

Objetivos: Descripción del contenido y aplicabilidad del Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata (CAVIPRES), tanto en su versión corta para la actividad clínica asistencial como su versión extendida para los protocolos de investigación.

Material y métodos: Se realiza una detallada revisión de las distintas áreas relacionadas con la calidad de vida de los pacientes con CP que recoge el CAVIPRES y se compara con los cuestionarios de CVRS adaptados disponibles.

Resultados: El CAVIPRES recoge información del apoyo social y de pareja, aspectos psicológicos del paciente, así como expectativas de vida frente a la evolución de la enfermedad junto a los parámetros clásicos sintomatológicos comunes al resto de los cuestionarios disponibles adaptados.

Conclusión: El CAVIPRES en su versión corta es un método adecuado, factible, válido, fiable y sensible al cambio en la evaluación de la CVRS de los pacientes con CP. La versión extendida de este es válida para su utilización en la investigación clínica. Ambos cuestionarios han sido donados a la Asociación Española de Urología por Abbott y se encuentran disponibles en la página web de la asociación (www.aeu.es).

Introduction

Prostate cancer (PC) is the second leading cause of cancer and the sixth leading cause of cancer-related death among males worldwide.[1] The number of PCs diagnosed has been increasing in recent years, and according to the most recent statistics, 1 out of every 6 males will suffer this tumor during their lives.[2] In the United States, the 5-year survival rate of patients with metastatic PC at diagnosis is 31%, but survival rate is virtually 100% if the disease is diagnosed in a localized stage.[3]

PC incidence in Spain is 45,33 cases per 100,000 inhabitants, and the condition causes more than 5,000 deaths annually.[4] Spain is therefore among the countries with less incidence of and mortality from this tumor as compared to other Western countries. However, it is expected that this is incidence will continue to increase and that prevalence causes this tumor to become a significant problem in our society because of the significant impairment in quality of life it causes.

The different effects that treatments and the disease itself may have on patient quality of life include urinary incontinence, bleeding, gastrointestinal toxicity, and erectile dysfunction.[5] A reference descriptive study in patients with PC showed that the main determinants of quality of life in these patients included bone pain, fatigue, sexual changes, and frequent interruption of their social activities.[6] All of these functional changes, together with the emotional burden of the disease, have a deep and long-lasting effect on the quality of life of patients.

Assessment of quality of life of patients with PC is a greatly significant parameter in both localized disease because of the long time period that patients will suffer the sequelae and in the advanced, metastatic stage of disease, where treatments have a modest impact on survival, but their adverse effects and the clinical symptoms from secondary disease sites may have a significant clinical impact on patients.[7]

Several instruments are currently available to specifically assess quality of life in patients with PC (table 1).[7] Direct comparisons of the different instruments for measuring quality of life in this disease are needed to identify the validity and extrapolation of results between them and their application in daily practice. Each of these instruments measures different quality of life variables in the patients.[8-14] Adequate interpretation of the results of these quality of life tests is influenced by the different clinical significance of the different parameters measured, and also by the limited training of physicians in these instruments.[7] However, many

Table 1 – Specific instruments for measuring quality of life in patients with prostate cancer. Adapted from Colloca et al[7]

Instrument	Characteristics
FACT-P[8]	Questions: 39 Time frame: past 7 days Areas: physical, social/familial, emotional, functional/well-being, relationship to physician, prostate cancer symptoms
EORTC-QLQ-PR25[9]	Questions: 46 Time frame: past 7 days Areas: overall health, physical function, occupational activity, emotional function, cognitive function, social function, symptoms (pain, fatigue, nausea, dyspnea, appetite loss, constipation, diarrhea, or insomnia), symptoms directly related to prostate cancer
UCLA-PCI[10]	Questions: 20 Time frame: past 4 weeks Areas: urinary, sexual, and intestinal function
EPIC[11]	Questions: 32 Time frame: past 4 weeks Areas: urinary function, bowel habits, sexual function, hormonal function, overall satisfaction
PROSQOLI[12]	Questions: 10 Time frame: past 24 h Areas: pain, physical activity, fatigue, appetite, constipation, family/marital relationship, mood, urine loss, general well-being
QOLM-P14[13]	Questions: 14 Time frame: past 7 days Areas: impact of pain on mobility, pain relief, sleepiness, hair loss, taste changes
CAVIPRES[14]	Questions: short version (CAVIPRES-20) and extended version (CAVIPRES-30) Time frame: past 4 weeks Areas: psychological aspects, hope and future, sex life, social and partner support, information and communication.

CAVIPRES: Spanish Questionnaire of Quality of Life in Patients with Prostate Cancer; EPIC: Expanded Prostate Cancer Index; EORTC-QLQ-PR25: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-PR25; FACT-P: Functional Assessment of Cancer Therapy-Prostate; PROSQOLI: Prostate Quality of Life Index; QOLM-P14: Quality of Life Module-Prostate Cancer 14; UCLA-PCI: University California Los Angeles-Prostate Cancer Index.

such questionnaires are adaptations of the original English questionnaires translated into Spanish, and there may be significant differences in interpretation of such questionnaires when they are completed by Spanish patients.

Understanding of the psychological health of males with PC is currently limited. However, the significance of this parameter is essential for overall patient health and for treatment acceptance and tolerability. There are studies suggesting a disproportionate impact of mental health impairment as compared to the clinical symptoms of the disease or the adverse effects of treatments in terms of overall quality of life of patients.[15]

The Spanish Quality of Life Questionnaire for Patients with Prostate Cancer (CAVIPRES) is a questionnaire developed and validated in the Spanish population and in the Spanish language which currently represents a manageable, reliable, sensitive, and specific tool for assessing the quality of life of patients with PC in Spain.[14] This questionnaire includes novel aspects such as life expectations about disease outcome and social and partner support which make it different from all other available instruments. In addition, CAVIPRES is adequate for use in clinical research of oncological prostatic disease.

This paper describes the contents and practical applicability of CAVIPRES in both its short and extended versions and for both daily care activities and clinical research projects in PC patients.

Materials and methods

The contents of both the short (CAVIPRES-20) and extended (CAVIPRES-30) versions of CAVIPRES are discussed in detail. CAVIPRES-30 consists of 30 questions or items analyzing five different domains: psychological aspects, hope and future, social and partner support, sex life, and information and communication. After questionnaire completion by the patient, a score is obtained. The higher the score, the better the health-related quality of life of the patient with PC.

CAVIPRES-20 is the short version of the questionnaire, intended to be used in daily clinical practice. This version consists of 20 questions and is shown in table 2. CAVIPRES-30 consists of 30 items, as shown in table 3.

No prospective, randomized studies directly comparing the results of the different instruments available for assessing the quality of life of patients with PC are available. A descriptive

Table 2 – Short version of the Spanish Questionnaire of Quality of Life in Patients with Prostate Cancer, to be used in daily clinical practice

Rate the following situations thinking about how you have felt in the past four weeks	In the past four weeks, how often have you been in this situation?				
	All of the time	Most of the time	About half the time	A little of the time	None of the time
Psychological aspects					
1. My disease worries me	1	2	3	4	5
2. I think of my disease	1	2	3	4	5
3. I am worried about feeling worse	1	2	3	4	5
4. My disease has a negative impact on my life	1	2	3	4	5
Hope and future					
5. I live the present with hope	1	2	3	4	5
6. I see the future with optimism	1	2	3	4	5
7. Despite my disease, I am able to enjoy life	1	2	3	4	5
Sex life					
8. I have trouble reaching orgasm	1	2	3	4	5
9. I have trouble ejaculating	1	2	3	4	5
10. I am not fully satisfied in my sexual relations	1	2	3	4	5
Social and partner support					
11. My family helps me with my disease and its treatment	1	2	3	4	5
12. Despite my disease and its consequences, I feel close to my partner	1	2	3	4	5
13. My partner helps me and cooperates to solve my sexual problems	1	2	3	4	5
14. I feel understood and supported by my friends	1	2	3	4	5
15. Healthcare professionals support me with regard to my impotence problem	1	2	3	4	5
Indicate your degree of agreement or disagreement with the following statements taking into account how you have felt in the past four weeks	*To what extent do you agree or disagree with the following statements?*				
	Totally agree	Agree	I am not sure	Disagree	Totally disagree
16. In general, I think that I need more information about my disease	1	2	3	4	5
17. I have felt the need to talk with someone about my disease	1	2	3	4	5
18. I think that exchanging experiences with other people would give me a little more confidence	1	2	3	4	5
19. I need to talk about the concerns or fears that my disease causes me	1	2	3	4	5
20. I would like to be alone with my doctor to ask him about all my doubts	1	2	3	4	5

comparison was made of the areas on which each of the available questionnaires are focused.

Results

Table 3 shows the composition of CAVIPRES-30, intended to be used for clinical research and consisting of 30 items distributed into five domains. Items 1 to 8 refer to psychological aspects, items 9 to 12 to hope and future aspects, items 13 to 18 to aspects related to sex life, items 19 to 24 to aspects related to social and partner support, and items 25 to 30 refer to aspects related to information and communication.

In order to have available in daily practice a useful and fast tool for assessing quality of life of patients with PC, a short version of the questionnaire called CAVIPRES-20 was developed (table 2). This consists of the same five domains or aspects but includes a lower number of items, so that psychological aspects are assessed using the first four items, hope and future issues are assessed using items 5-7, the sex

Table 3 – Extended version of the Spanish Questionnaire of Quality of Life in Patients with Prostate Cancer, to be used in clinical research

Rate the following situations thinking about how you have been in the past four weeks	In the past four weeks, how often have you been in this situation?				
	All of the time	Most of the time	About half the time	A little of the time	None of the time
Psychological aspects					
1. My disease worries me	1	2	3	4	5
2. My disease prevents me from living a normal life	1	2	3	4	5
3. I think of my disease	1	2	3	4	5
4. I need to talk about the concerns or fears that my disease causes me	1	2	3	4	5
5. It worries me how my disease will evolve	1	2	3	4	5
6. I am worried about feeling worse	1	2	3	4	5
7. My disease has a negative impact on my life	1	2	3	4	5
8. It bothers me that I am considered as a cancer patient	1	2	3	4	5
Hope and future					
9. I live the present with hope	1	2	3	4	5
10. I see the future with optimism	1	2	3	4	5
11. Despite my disease, I am able to enjoy life	1	2	3	4	5
12. My disease makes me appreciate more some things of life	1	2	3	4	5
Sex life					
13. I have erection problems	1	2	3	4	5
14. I have trouble reaching orgasm	1	2	3	4	5
15. I have trouble ejaculating	1	2	3	4	5
16. I feel that my sex life has ended because of my disease	1	2	3	4	5
17. I have lost interest in sex because of my disease	1	2	3	4	5
18. I am not fully satisfied in my sexual relations	1	2	3	4	5
Social and partner support					
19. My family helps me with my disease and its treatment	1	2	3	4	5
20. Despite my disease and its consequences, I feel close to my partner	1	2	3	4	5
21. Although my partner understands me, I am still worried about my erection problem	1	2	3	4	5
22. My partner helps me and cooperates to solve my sexual problems	1	2	3	4	5
23. I feel understood and supported by my friends	1	2	3	4	5
24. Healthcare professionals support me with regard to my impotence problem	1	2	3	4	5

Indicate your degree of agreement or disagreement with the following statements taking into account how you have felt in the past four weeks	*To what extent do you agree or disagree* statements? *with the following*				
	Totally agree	Agree	I am not sure	Disagree	Totally disagree
25. In general, I think that I need more information about my disease	1	2	3	4	5
26. In general, I think that I should have been given more information about the sequelae I would have	1	2	3	4	5
27. I would like a support service for people who have this disease	1	2	3	4	5
28. I have felt the need to talk with someone about my disease	1	2	3	4	5
29. I think that exchanging experiences with other people would give me a little more confidence	1	2	3	4	5
30. I would like to be alone with my doctor to ask him about all my doubts	1	2	3	4	5

life domain is assessed with items 8-10, social and partner support is evaluated with items 11-15, and aspects related to information and communication are assessed using items 16-20.

During development and validation of these questionnaires, 69% of patients reported that the extended version of the questionnaire was "easy" to complete.[14] In addition, 76% of patients completed this questionnaire version in less than 20 min.

Table 1 shows the characteristics of the main questionnaires used for assessing the quality of life of patients with PC. As shown by the comparison of the different properties of questionnaires, the weight of social/family aspects, and mainly of patient perception of life when faced with disease outcome (hope and future), is greater in CAVIPRES as compared to all others.

Discussion

Multiple treatment options are available for patients with both localized and advanced PC. A multidisciplinary approach is required for treatment of PC. Urologists, radiologists, pathologists, radiotherapists, and medical oncologists should act simultaneously or sequentially in order to provide the patient with the best alternative available depending on disease stage and clinical characteristics of the patient. However, patients are often excluded from the process when decisions about their treatment are taken.

Because of its incidence, but mainly because of its prevalence, PC is a major healthcare problem. Better surgical procedures, more advanced technology in the radiation field, and more effective drugs are increasingly available for both hormone-refractory and hormone-sensitive disease. As a result, the longer survival of these patients, combined with the increased median age of the population, increases the prevalence rates of this tumor. The overall number of PC patients with a relatively long median survival makes mandatory a serious consideration of their quality of life during the years they will live with the disease.

In addition, it should not be forgotten that elderly patients have unique characteristics that make them particularly sensitive to different treatment options or attitudes when facing diseases. Although chronological and biological ages are not necessarily equivalent, aging causes physiological changes in organ functions and drug pharmacokinetics.[16]

Since survival benefits may decrease and toxicity risks of drugs may increase with age, preservation and improvement of quality of life should be among our main objectives in the elderly. In daily practice, quality of life is understood as the maintenance of the physical functions of patients, together with an acceptable symptom control.[17]

Overall assessment of the quality of life of patients should not only include the symptoms or organic functions caused by the disease or treatments, but also provide information about the psychological and social impact of the disease on the patient.[18] Thus, questions about the overall quality of life of patients differ from the quality of life scales of the disease itself because patients consider what they actually think that is important for them. Therefore, patients score their health state on the one hand and, on the other hand, their overall quality of life, which is influenced by other different factors.[19] Various approaches have been developed to interpret quality of life scales. No standard method is available to interpret the different quality of life instruments, so that interpretation of results is often based on statistical significance, which does not necessarily correlate to clinical significance.[20]

Specific instruments for measuring the quality of life in patients with PC have mainly focused on five health domains. The University California Los Angeles-Prostate Cancer Index (UCLA-PCI)[10] was validated in 1998 and measures areas related to urinary symptoms and sexual and intestinal activity. The Expanded Prostate Cancer Index (EPIC) subsequently added urinary incontinence and vitality subscales.[11] There are other instruments, previously discussed, incorporating in some cases analyses of social and relation aspects of the patient. A direct comparison of quality of life studies in PC patients is not possible because of the many different instruments used in them to measure quality of life. It is therefore essential to develop instruments to assess quality of life in these patients which are as homogeneous as possible.[21] Of the six adapted international questionnaires analyzed, three (UCLA-PCI,[10] EPIC,[11] and Quality of Life Module-Prostate Cancer 14 [QOLM-P14][13]) do not include social or psychological aspects of patients in any of their items or domains.

Numbers of items range from 10 in the Prostate Quality of Life Index (PROSQOLI)[12] and 46 in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-PR25.[9] The number of different domains in the questionnaire also ranges from five (Functional Assessment of Cancer Therapy-Prostate,[8] EPIC,[11] QOLM-P14,[13] and CAVIPRES[14]) and nine (PROSQOLI questionnaire).[12]

The time frame to be considered for answering questionnaire items may also change test results. Thus, there are questionnaires that only question patients about events related to their quality of life in the past 24 hours (PROSQOLI[12]), whereas most of them refer to the past week (Functional Assessment of Cancer Therapy-Prostate,[8] European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-PR25,[9] and QOLM-P14[13]) or the past four weeks (UCLA-PCI,[10] EPIC[11] and CAVIPRES[14]).

CAVIPRES was developed and validated in more than 1,200 Spanish patients in three phases over three years.[14] A good correlation was shown between the quality of life levels provided by this and other instruments in terms of both general (SGF-36) and PC-specific (UCLA-PC) quality of life. CAVIPRES is currently considered to be a feasible, reliable, and sensitive to change instrument for measuring quality of life, and is therefore helpful in both daily clinical practice and clinical research.

CAVIPRES consists of 20 or 30 questions, depending on whether the short or extended versions are required (table 2 and 3). Items or questions are divided into five patient domains: psychological aspects, hope and future, sex life, social and partner support, and information and communication. In the short version, four items are used to define psychological aspects, three to define hope and future, three for sex life, five for social and partner support, and another five items for defining information and communication aspects. The extended version includes eight items to try and define psychological aspects, four for hope and future, six for sex life, six for social and partner support, and another six items to try and assess the information and documentation domain.

All four domains include questions that should be answered in a 5-point Likert scale (1=all of the time and 5=none of the time). The higher the score, the better patient perception of quality of life. CAVIPRES includes two novel and characteristic domains as compared to all other adapted questionnaires available. The first of these is a social and partner support domain to assess impact of PC on the immediate patient environment, while the second is intended to assess patient perceptions of life expectations in terms of disease outcome (hope and future).

The questionnaire is highly reliable, as shown by the Cronbach's alpha coefficient (r=0.77) obtained for the overall score and scores for each domain. CAVIPRES has also been shown to have a high test-retest reproducibility, with an inter-class coefficient of 0.92.[14]

CAVIPRES questionnaires were developed by the Work Group on Quality of Life in Prostate Cancer and its sponsor, Abbott Laboratories S.A. Spain. CAVIPRES has been donated by Abbot to the Spanish Association of Urology (AEU). All urologists who are AEU members have therefore available the questionnaires for online downloading at the AEU website (www.aeu.es). Researchers who are not AEU members and want to use the questionnaires must send a letter/e-mail asking for permission to use them to the AEU Secretariat (aeu@aeu.es) (see appendix 1. Instructions for access to CAVIPRES questionnaires).

The short version of the questionnaire may be used as the requesting urologist deems appropriate. The extended version may be used in any clinical study, but the authors should mention in the study methods the source of the questionnaire (AEU) and include the appropriate reference in the reference list.[14]

CAVIPRES is a unique instrument developed in an attempt to address all aspects that may possibly have an impact on patient quality of life. However, the value of quality of life questionnaires for patients with PC has not been determined yet. Indeed, the health status of patients is more influenced by physical function, while their overall quality of life appears to be more affected by their emotional state. Achievement of an agreement between the state of health perceived and overall quality of life should be our main objective.[7]

Conclusions

Because of the wide range of treatment options available for patients with both advanced and localized PC, the different adverse effects of therapeutic procedures, and the different symptoms experienced by patients, considerations about health-related quality of life should have a significant role in the decision-making process.

CAVIPRES was developed and validated in Spain and is adequate for use in both daily clinical practice and clinical research. Both the short and extended versions of the questionnaire have been donated by Abbott to the AEU and are available at the AEU website.

Conflict of interest

Abbott Laboratories S.A. provided funding for manuscript preparation. Dr. Rebollo states that he works for and is a shareholder of Abbott.

All other authors state that they have no conflicts of interest in this publication.

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Appendix 1 - Instructions for access to the Spanish Questionnaires of Quality of Life in Patients with Prostate Cancer for members and non-members of the Spanish Association of Urology

AEU members	Enter the AEU website (aeu.es) and access the Publications area, from which the short (CAVIPRES-20) or extended (CAVIPRES-30) questionnaire can be downloaded online, depending on the intended use
Non-AEU members	Questionnaires should be requested by post or e-mail, stating the reason or the title of the study to be conducted, to the AEU Secretariat (aeu@aeu.es), which will internally process the request and reply within 15 days
Reference to the questionnaire in scientific publications	When questionnaires are used as part of the methods of a research study, authors should mention the article listed as reference no. 14: Gómez-Veiga F, Cozar-Olmo JM, Günthner S, Puyol-Pallas M, Silmi-Moyano A, Baró-Ramos E, Rebollo FJ. Desarrollo y validación del primer CAVIPRES, basado en la percepción del paciente. Actas Urol Esp. 2009;33:623–34. This same article must also be included in the reference list.

AEU: Spanish Association of Urology; CAVIPRES: Spanish Questionnaire of Quality of Life in Patients with Prostate Cancer.

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