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RESEARCH ARTICLE

Sexual dysfunction in patients with cancer, a challenge in oncology practice: results of the CLARIFY project

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Abstract

Background Sexual dysfunction (SD) associated with oncological treatment is a common and understudied disorder. Our aim was to characterize SD in a cohort of Spanish patients.

Methods Analytic observational study in patients included in the CLARIFY H2020 project at the Hospital Universitario Puerta de Hierro. Clinical variables and validated measures of sexual function were collected from October 2020 to May 2022. Frequency and quality of sexual activity were assessed. Descriptive, trend associations, and logistic regression analyses were performed.

Results A total of 383 patients were included: breast cancer 68.14% (261), lung cancer 26.37% (101), and lymphoma 5.50% (21). Mean age was 56.5 years (range 33–88). 19.58% (75) were men and 80.42% (308) were women. 69% and 31% of men and women, respectively, reported being sexually active. The absolute frequency of overall sexual dissatisfaction was 76% in women and 24% in men. Women with breast cancer were most likely to have severe sexual dysfunction. Those with early disease had resolved complaints after 5 years. In multinomial logistic regression, significant associations were found in women with metastatic breast cancer and severe disorders of arousal (p 0.000), lubrication (p 0.002), orgasm (p 0.000), as well as dissatisfaction with sexual performance (p 0.000) and global sexual dissatisfaction (p 0.000). Women with lung cancer have severe arousal dysfunction (p 0.016) and global sexual dissatisfaction (p 0.044).

Conclusions Our population has a high prevalence of SD, which supports the need to increase awareness of this disorder among the medical oncology team and the importance of including sexual health assessment in oncological patient follow-up.

Keywords Cancer · Long survivors · Sexual dysfunction · Oncological treatment · Cohort studies

Introduction

Advances in cancer diagnosis and treatments have led to the emergence of an increasing number of survivors patients. Oncological approaches incorporate surgery, radiotherapy, and systemic treatments including chemotherapy, and new alternatives such as immunotherapy with immune checkpoint inhibitors and targeted therapy. These interventions may generate physical changes and adverse short- and long-term psychosocial effects in patients. Sexual dysfunction (SD) is a common and long-lasting effect that can be caused by the biological, physiological, and psychological dysfunctions secondary to cancer itself and oncological treatments [1–5].

SD has been described in the general population with a frequency of 40–45% in women and 30–60% in men and has been identified as an important clinical condition affecting quality of life. It is well known that the prevalence of SD increases with age and with the presence of co-morbidities such as diabetes mellitus and obesity. [6–8]

There are few reports of SD in oncological patients, but it is well documented that nearly all cancer treatments have the potential to affect sexual health and that SD affects quality of life during and after oncological treatments by resulting in sexual response disturbances as well as psychosocial disorders such as depression and anxiety. [1, 2, 4, 9]

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Overall, in patients with cancer, some characteristics have been suggested as risk factors for SD such as age, presence of solid neoplasm in the pelvis, diagnosis of hematologic malignancy, administration of stem cell transplantation and alkylating agents, as well as total body irradiation. [1, 3, 4]

The prevalence of SD in oncological population has been described between 40 and 100%, which may differ according to the type of neoplasm. The disorders of sexual health are related to the extent of oncological therapies received and their route of administration, whether systemic or local. Some cancer treatments can have a significant and direct impact on sexuality. For example, cancer surgery can cause body image problems due to scarring and changes in physical appearance. On the other hand, radiation therapy, especially when delivered to the pelvis, can damage adjacent organs. [1–4, 10–15]

It is important to note that most of the literature on SD in cancer patients is derived from patients with breast cancer, prostate cancer, and reproductive cancers such as cervical and uterine cancer. These data are often inappropriately extrapolated to patients with other malignancies, who may experience different types of disturbances in sexual function. [6, 9, 10]

Therefore, it is important that the medical oncology team adequately address SD according to the type of malignancy to provide tailored and effective support to minimize the long-term effects of cancer treatments and improve the quality of life of patients. [1, 4]

Therefore, one of the objectives of the CLARIFY H2020 (Long-term Artificial Intelligent Follow-up of Cancer Survivors) project was to investigate the incidence and prevalence of long-term effects in cancer patients following cancer treatment, including quality of life and sexual dysfunction. Since there are no guidelines for the long-term management and follow-up of SD in patients with cancer, this research was developed to determine the characteristics of this condition to promote changes in current oncology clinical practice based on the results.

Methods

Design, population, and sample

This is analytical observational study aimed to identify and describe the characteristics of SD in patients with cancer and to explore risk factors associated with this disturbance. The study population was a cohort of Spanish patients included in the CLARIFY H2020 (Cancer Long Survivors Artificial Intelligence Follow-up) project at the Hospital Universitario Puerta de Hierro HUPH in Majadahonda, Madrid.

Table 1 General characteristics of the population

All patients	*n* 383
Diagnosis	
Breast cancer	68.1% (261)
Lung cancer	26.3% (101)
Lymphoma	5.5% (21)
Average age	56.5 years (range 33–88)
Marital status	
Married	72.5%
Separated/divorced	14.3%
Single/ single woman	7.5%
Widowed/widow	5.0%
Missing	0.5%
Educational level	
University	52.7%
Intermediate	32.3%
Basic	13.8%
Without education	1.04%
Rate response to SF* Questionnaire	
Early breast cancer	73.2%
Metastatic breast cancer	40.3%
Men with lung cancer	74.6%
Women with lung cancer	58.8%
Men with lymphoma	85.7%
Women with lymphoma	69.2%
Type of cancer treatment	
Breast cancer	68.1% (261)
Chemotherapy for metastatic disease	10.7% (28)
Hormone therapy for metastatic disease	10.7% (28)
Chemotherapy for early disease	18.0% (47)
Hormone therapy for early disease Dx** < 5 years	24.5% (64)
Hormonal therapy Dx* > 5years	21.0% (57)
Follow-up without treatment Dx* > 5 years	10.0% (25)
Follow-up without treatment Dx* < 5 years	5.0% (12)
Men with lung cancer	66.3% (67/101)
Chemotherapy	27.0% (18)
Immune check point inhibitors	36.0% (24)
Targeted therapy	12.0% (8)
Immunotherapy plus chemotherapy	5.00% (4)
Follow-up	20.0% (13)
Women with lung cancer	33.66% (34/101)
Chemotherapy	35.2% (12)
Immune check point inhibitors	26.7% (9)
Targeted therapy	23.5% (8)
Immunotherapy plus chemotherapy	8.8% (3)
Follow-up	6.0% (2)

*SF Sexual function **Dx: time from diagnosis

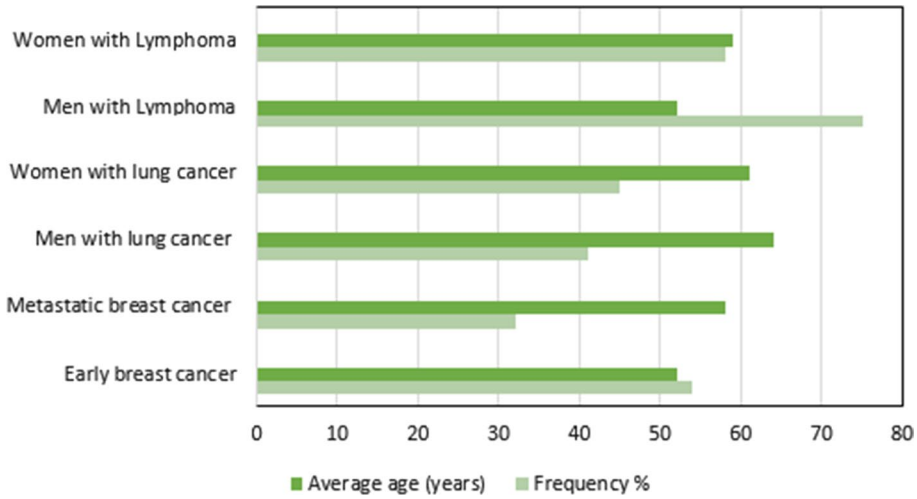


Fig. 1 Frequency of sexual activity during the last 4 weeks (DFSA) according to type of neoplasm, gender, and median age

Table 2 Groups according diagnosis, gender and oncological treatment

Group number	% (*n* 383)	Group name
1	7.31 (28)	Patients with metastatic breast cancer receiving chemotherapy
2	7.31 (28)	Patients with metastatic breast cancer receiving hormonal treatment or monoclonal antibodies
3	11.74 (45)	Patients with early breast cancer receiving chemotherapy
4	16.71 (64)	Patients with treated early breast cancer, diagnosis less than 5 years receiving hormone therapy
5	3.13 (12)	Patients with treated early breast cancer, diagnosis less than 5 years in follow-up without treatment
6	14.5 (57)	Patients with breast cancer diagnosis more than 5 years receiving hormone treatment
7	6.50 (25)	Patients with breast cancer diagnosis more than 5 years without treatment
8	0.50 (2)	Patients with breast cancer diagnosis less than 5 years previous treatment with anthracyclines
9	18.0 (67)	Men with lung cancer
10	8.9 (34)	Women with lung cancer
11	2.0 (8)	Men with lymphoma
12	3.4 (13)	Women with lymphoma

The CLARIFY project was designed to be conducted over three years with a retrospective and prospective cohort and was divided into three phases; the first two phases collected information on neoplasm and type of treatment, including acute effects of treatment and relevant clinical outcomes. The third phase included the identification of long-term non-tumor-related outcomes including assessing quality of life and sexual function.

Enrollment, monitoring, and data processing procedure

Patients were screened between October 2020 and May 2022. Inclusion criteria were: age over 18 years, patients diagnosed with: lung cancer stages IB–IV, early and metastatic breast cancer, and lymphoma who were in follow-up or under active cancer treatment. Potentially eligible patients seen at the outpatient clinic from the time of enrollment were invited to participate. Informed consent was obtained from all patients in person during the medical care provided by the oncologists prior to the start of participation.

Table 3 Distribution of absolute frequencies of global sexual satisfaction (GSS)

Group	Dissatisfaction	Moderate satisfaction	Complete satisfaction
Metastatic breast cancer	22.1%	9,8%	7.5%
Early breast cancer	35.9%	36.5%	25.4%
Breast cancer long follow-up	15.4%	29.3%	26.1%
Men with lung cáncer	8,8%	2.4%	10.6%
Women with lung cáncer	2.8%	0%	5%
Men with Lymphoma	14.4%	19.5%	20.5%
Women with lymphoma	0.6%	2.5%	3.7%
Total	100%	100%	100%

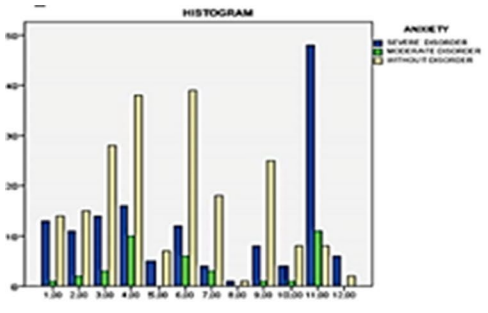


Figure 2.5.A

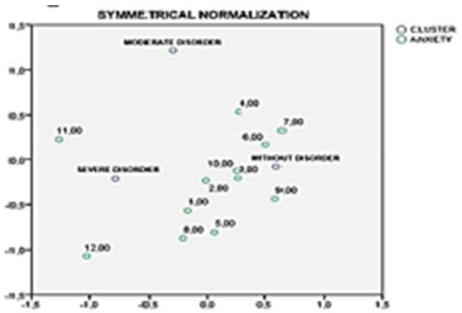
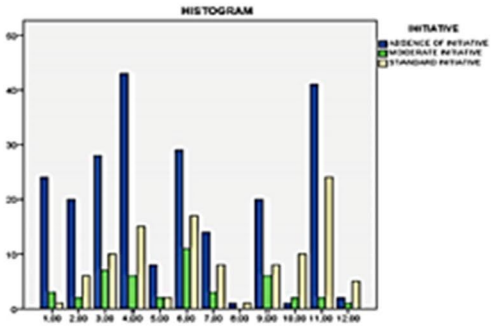


Figure 2.5.B



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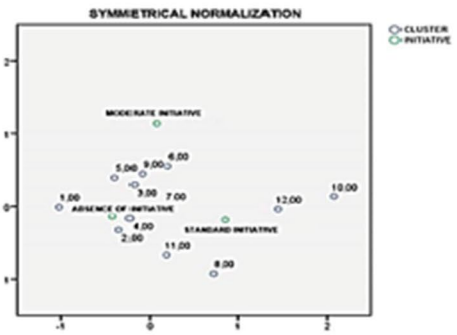

Figure 2.6.B

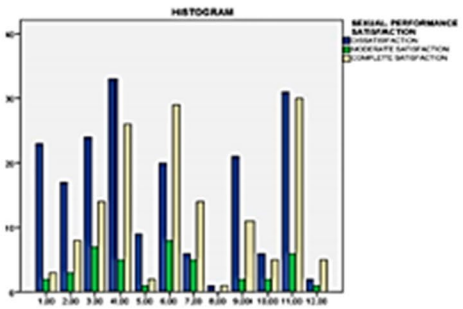

Figura 2.7.A

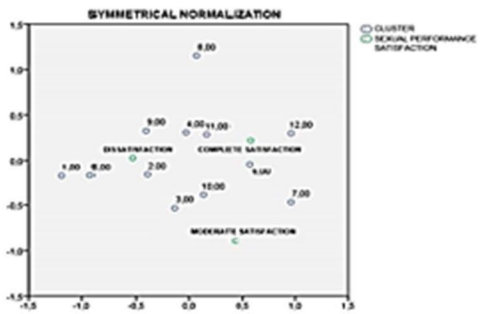

Figura 2.7.B

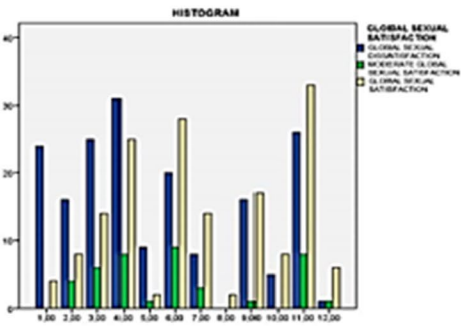

Figura 2.8.A

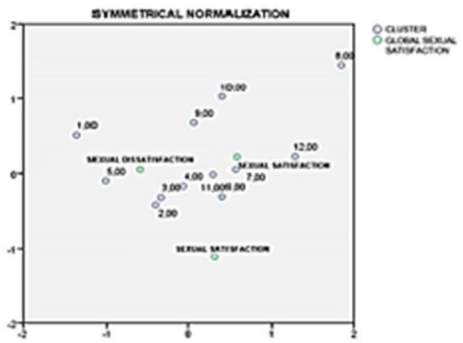

Figura 2.8.B

◂**Fig. 2** Domains evaluating the phases of sexual response (DESR) two correspondence analysis graphs. Figure 2.1.**A** Bar chart for distribution of desire disorder. Figure 2.1.**B** Two-dimensional correspondence analysis for desire disorders. Figure 2.2.**A** Bar chart for distribution of arousal disorder. Figure 2.2.**B** Two-dimensional correspondence analysis for arousal disorders. Figure 2.3.**A** Bar chart for distribution of lubrication disorder. Figure 2.3.**B** Two-dimensional correspondence analysis for lubrication disorders. Figure 2.4.**A** Bar chart for distribution of Orgasm disorder. Figure 2.4.**B** Two-dimensional correspondence analysis of Orgasm d. Figure 2.5.**A** Bar chart for distribution of anticipatory anxiety disorder Figure 2.5.**B** two-dimensional correspondence analysis for Anticipatory anxiety disorders. Figure 2.6.A Bar chart for distribution of sexual initiative disorder. Figure 2.6.**B** Two-dimensional correspondence analysis for sexual initiative disorder. Figure 2.7.**A** Bar chart for distribution of sexual performance satisfaction. Figure 2.7.**B** Two-dimensional correspondence analysis for sexual performance. Figure 2.8.**A** Bar chart for distribution of global sexual satisfaction Figure 2.8.**B** Two-dimensional correspondence analysis for global sexual satisfaction

Variables of interest

Clinical variables and demographics were assessed. Measures of sexual function were obtained by electronic or physical completion of two gender-specific validated sexual function questionnaires: the sexual function questionnaire for women (SFQW) and the sexual function questionnaire for men (SFQM). [16, 17] These instruments were validated and translated into Spanish several years ago by a local research group in the community of Valencia (Spain) and are available for use in primary care settings.[16, 17]

The 5–10 min questionnaires had 14 questions for women and 12 questions for men, and included evaluations of sexual response phase criteria according to DSM IV (for women) and DSM V (for men). The domains assessing sexual response phases (DESR) included desire, arousal and lubrication, and orgasm, satisfaction with sexual performance, global sexual satisfaction, anticipatory anxiety, and sexual initiative. Measures were self-reported by participants on a scale of 1–5, which allowed categorization as severe, moderate, or no dysfunction. In addition, a description of the frequency of sexual activity in the past four weeks (DFSA) was assessed with one specific question [16, 17].

These questionnaires were selected for their ability to be self-administered, their history of effectiveness in assessing overall sexual function in the general population, and for their low level of complexity. [16, 17]

Statistical analysis

An univariate analysis method was used for descriptive analysis. Qualitative variables were determined with absolute and relative frequencies and quantitative variables with measures of central tendency and dispersion, using the mean and standard deviation for variables with normal distribution and the median and interquartile range for variables with non-normal distribution. Subsequently, an inferential analysis was performed with chi2 distribution to evaluate the correlations between the variables and the main outcomes in the measurement of sexual function.

Given the large number of variables to be correlated, possible trends of association were evaluated through of graphical statistical technique using multiple correspondence analysis. In addition, multinomial logistic regression was performed; to avoid bias, the model was adjusted for age, type of treatment, type of cancer, and time of diagnosis.

The goodness of fit of the model was evaluated using the Hosmer and Lemeshow statistic and the predictive ability through the Omnibus test. A summary was performed, in which -2 log-likelihood (-2LLL) was used to determine the fit to the data. The proportion of variance of the dependent variable was calculated using Cox's and Snell's R-squared and Nagelkerke's R-squared.

Ethical aspects

This study adhered to the ethical principles of the Declaration of Helsinki (2013). The information was guaranteed to be for scientific purposes only, and the right to privacy was protected by omitting the identifying data of the study subjects. The protocol of this research was submitted and approved by the local ethics committee of HUPH.

Results

383 patients were included in the analysis. The average age of the population was 56.5 years (range 33–88). 19.58% (75) of patients were men and 80.42% (308) were women. Regarding marital status, 72.57% were married. Concerning the level of education, 52.74% had a university degree (Table 1). The global rate response to the sexual function questionnaires by the participants was 66.96%.

When describing frequency of sexual activity in the last four weeks (DFSA), 69% of men and 31% of women reported being sexually active. In general, DFSA was different according to gender, type of neoplasm, and mean age of patients (Fig. 1).

According to diagnosis and oncological treatment, we classified the whole population in 12 subgroups. The majority of patients were women with breast cancer, with a preponderance in the early-stage group receiving hormone therapy. (Group 4). Table 2.

As for the domains evaluating the phases of sexual response (DESR), the absolute frequency of overall sexual dissatisfaction (AGSD) was 76% in women and 24% in men. Global sexual dissatisfaction(GSD) results for all subgroups

are shown in Table 3. DESR association trend analysis by multiple correspondence showed that women with metastatic breast cancer (group 1) presented the highest tendency to severe disorders of most of the phases of sexual response including desire, arousal, orgasm, sexual initiative, and satisfaction with sexual performance. While those women with breast cancer under follow-up receiving hormonal therapy (group 4) had moderate disorders of desire and arousal, and those with time of diagnosis more than 5 years (group 7) tended not to present alterations (Fig. 2).

In relation to the patients with lung cancer, the men (group 9) had the highest tendency to have severe disorders of desire, arousal, and orgasm. On the other hand, men with lymphoma (group 11) tended to have no disorders.

In the multinomial logistic regression analysis, women with metastatic breast cancer were more likely to suffer from severe disorders of arousal (p 0.000), severe disorder of lubrication (p 0.002), severe disorder of orgasm (p 0.000), as well as dissatisfaction with sexual performance (p 0.000) and global sexual dissatisfaction (p 0.000). Likewise, in women with early breast cancer, the most frequent findings were severe disorder of desire (p 0.004), severe disorder of orgasm (p 0.003), and dissatisfaction with sexual performance (p 0.000). While, women with lung cancer showed severe arousal disorder (p 0.016) and global sexual dissatisfaction (p 0.044). Multinomial logistic analysis is summarized in Table 4.

Discussion

In despite of the high frequency of sexual dysfunction related with cancer treatment, sexual problems are usually not adequately discussed with patients during medical care for a variety of reasons.

Dissatisfaction with the information provided by clinicians was reported in up to 50% of oncological population. Time constraints, lack of training, religious beliefs, and differences in access and insurance were cited by healthcare professionals as the main barriers to sexual function assessment [2–5].

This study aimed to identify and describe the characteristics of SD in a cohort of Spanish patients with cancer to develop strategies to integrate sexual health into routine care and improve the quality of life of survivors patients.

Limitations of our research include the observational design, which is known to introduce bias, and the participation of a single health care institution. Therefore, the dominant population in this research is women with breast cancer, and they influence our findings. Thus, efforts were made to analyze the results in this context and to interpret the results appropriately.

Our study population was average age less than 60 years (56.5 years). The most frequent tumor was breast cancer (68 %) which is consistent with epidemiological data on cancer prevalence worldwide [18]. Response rates to the sexual function questionnaire were high, with the highest response rate in men with lymphoma (86%) and the lowest in women with metastatic breast cancer (40%). The high acceptance of participation could be due to the high educational level of our population (52% university graduates) and the motivation of patients to have the opportunity to communicate their sexual function problems. In addition, the use of a self-administered instrument may avoid nonresponse due to fear of being identified in a personal interview [16, 17]. The lower response in patients with metastatic breast cancer is secondary, as they are the group of our study population with the most symptoms and worsening of quality-of-life scales.

Interestingly, we found a significant difference between men and women (69 vs. 31%) in the frequency of sexual activity in the past 4 weeks (DFSA) as descriptive measure of sexual dysfunction. Specifically, young men with lymphoma and women with early breast cancer had the highest frequency of sexual activity (median age: 52 years). These findings are like previous reports in the North American general population, where SD frequency is related with aging [2, 6, 8]. Additionally, our study evidenced high absolute frequency of global sexual dissatisfaction (GSD) in women (76%), specifically in women with early breast cancer and women with lung cancer; and lower GSD in men with lymphoma and men with lung cancer.

On a more specific level, in the study population, women with metastatic breast cancer who received chemotherapy had the greatest tendency to suffer from severe disorders in almost all phases of sexual response, including desire, arousal, orgasm, sexual initiative, and satisfaction with sexual performance. While those receiving hormonal treatment tended to suffer moderate disorders of desire and arousal. On the other hand, those women with breast cancer and time of diagnosis of more than 5 years tended to report no disorders. These findings suggests that SD is more frequent and severe in cases of metastatic neoplasms and in patients with early stages at the beginning of chemotherapy treatment and hormonal therapy but tends to improve over time in long survivors with more than 5 years of diagnosis.

The improvement of sexual dysfunction in relation to the time of administration of oncological treatment suggests that this alteration in our patients will not be attributable to menopause and that oncological treatment had influenced the whole clinical condition.

In the available literature, we found no specific reports on the influence on SD of type, duration and time of oncological treatment. The most frequently described risk factors

Table 4 Statistically significant associations according to sexual response phase criteria, neoplasia, age, and tumor stage

Breast Cancer	
1. Desire	
Severe disorder	
Early breast cáncer	p 0.004 OR 3.918 IC 95% (1.535-10.10)
Long-term survivors breast cancer	1 ref.
Moderate disorder	
Moderate disorder	p 0.001 OR 4.98 IC 95% (1.99-12, 48)
Long-term survivors breast cancer	1 ref
2. Arousal	
Severe disorder	
Metastatic breast cáncer	p 0.000 OR 9.6 IC 95% (3.10-29,89)
Long-term survivors breast cancer	1 ref.
3. Lubrication	
Severe disorder	
Metastatic breast cancer	p 0.002 OR 4.4 IC 95% (1,74-11.11)
Long-term survivors breast cancer	1 ref.
Breast cancer 65-74 years	p 0.002 OR 4.4 IC 95% (1, 74-11.11)
Long-term survivors breast cancer	1 ref.
Breast cancer 65-74 years	p 0.029. OR 3.84 IC 95% (1.15-12.8)
Breast cancer 35-44 years	1 ref.
4.Orgasm	
Severe disorder	
Metastatic breast cancer	p 0.000 OR 4.82 IC 95% (2.11-10.97)
Early breast cancer	p 0.003 OR 2.55 IC 95% (1.36-4.77)
Long-term survivors breast cancer	1 ref.
Breast cancer 65-74 years	p 0.004. OR 3.16 IC 95% (1.05-9.51)
Breast cancer 35-44 years	1 ref.
5.Satisfaction sexual performance	
Dissatisfaction	
Metastatic breast cancer	p 0.000 OR 5.14 IC 95% (2.19-12.06)
Early breast cancer	p 0.000 OR 2.61 IC 95% (1.37-4.98)
Long-term survivors breast cancer	1 ref.
6. Global sexual satisfaction	
Dissatisfaction	
Metastatic breast cancer	p 0.000 OR 4.4 IC 95% (1.94-10.22)
Long-term survivors breast cancer	1 ref.
LUNG CANCER	
1.Arousal	
Severe disorder	
Women with lung cancer	p 0.016 OR 13.8 IC 95 %(1.63-116.69)
Men with lung cancer	1 ref.
2. Global sexual satisfaction	
Dissatisfaction	
Women with lung cancer	p 0.044 OR 3.12 IC 95% (1.02-9.51)
Men with lung cancer	1 ref.
Lung Cancer	
1.Arousal	
Severe disorder	
Women with lung cancer	p 0.016 OR 13.8 IC 95 %(1.63-116.69)
Men with lung cancer	1 ref.
2. Global sexual satisfaction	
Dissatisfaction	
Women with lung cancer	p 0.044 OR 3.12 IC 95% (1.02-9.51)
Men with lung cancer	1 ref.

*age did not behave as an effect-modifying variable in multinomial logistic regression in lung cancer patients. **Only statistically significant associations that ran in all multinomial models are reported

have been breast surgery scar and had received some oncological treatment [19–23].

Furthermore, the lack of adequate data collection instruments to assess sexual function and the heterogeneity of the published data are important features that make difficult to obtain the complete and real knowledge of the problem [22].

Our data in women with lung cancer are particularly relevant and innovative because a large percentage of these patients are receiving new oncological treatments, such as immune checkpoint inhibitors and targeted therapies, for which there is a lack of information on their impact on sexual function.

An earlier study of women with lung cancer found that 95% of these patients had sexual function scores below the 50th percentile [24]. In another more recent research, 64% of women with advanced lung cancer, nearly half of whom were receiving targeted therapy, were found to have moderate to severe sexual dysfunction in 77% [25].

Among our female patients with lung cancer (n 34), 35.29% were receiving chemotherapy, 26.47% were receiving immunotherapy, and 23.52% were receiving targeted therapy, these findings add evidence to the high prevalence of sexual dysfunction in patients with this neoplasm and reinforces it is critical to also consider the role of new antineoplastic therapies such as immune check point inhibitors and targeted therapy as factors associated with SD.

According to these findings, oncologists must recognize that patients' sexual needs are unique by gender, treatment, and tumor type, and provide resources and care tailored to different populations.

Educating all members of the medical oncology team, patients and caregivers about sexual health remains a priority to overcome the stigma associated with sexual function following cancer diagnosis and treatment. This requires a multidisciplinary team with seamless communication between specialists in oncology, psychology, psychiatry, urology, and gynecology.

Future research with a larger and more diverse group of patients is needed to further investigate the impact of factors such as gender and specific oncologic treatment on sexual function according to the type of malignancy. This information will help to gain a deeper understanding of the problem and to modify current oncologic follow-up guidelines to include sexual health as one of the parameters to be screened by oncologist and supported by multidisciplinary team.

All these measures will improve the quality of life of patients and contribute to the reduction of inequalities in their medical care.

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Data availability The data that support the findings of this study are available from the corresponding author, [AVO], upon reasonable request.

Declarations

Conflict of interest AVO reports consultant fees from AstraZeneca, Bristol Myers Squibb Company, Pfizer, Merck, Takeda Oncology and Roche; and support for attending meetings and/or travel from Pfizer, Roche, MSD and Janssen. VC reports consultant fees form Roche, BMS, MSD, Astrazeneca, Takeda, Pfizer, Lilly, AMGEN and Sanofi and support for attending meeting and/or travel: Takeda, Roche. ND reports consultant fees from Merck, Mirati, Regeneron, Pfizer, Astrazeneca, DSI, BMS and neogenomics MP reports consultant fees from AstraZeneca, Bristol Myers Squibb Company, Eli LIlly, F. Hoffmann-La Roche, Janssen, Pfizer, MSD, Takeda Oncology and Roche; and support for attending meetings and/or travel from AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb Company, Eli LIlly, F. Hoffmann-La Roche, Pierre Fabre Pharmaceuticals, Takeda Oncology and Roche. The ohers authors have no conflicts of interest to declare. This paper is part of the CLARIFY project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme under grant agreement No. 875160. 7 The contents in this article are those of the author(s) and do not necessarily reflect the official opinion of the European Union. Neither the European Union institutions and bodies nor any person acting on their behalf may be held responsible for the use which may be made of the information contained therein.

Ethical approval This study adhered to the ethical principles of the Declaration of Helsinki (2013). The use of information exclusively for scientific purposes was guaranteed, and 6 the right to privacy was protected by omitting the identifying data of the participating subjects. The protocol for this research was presented to and approved by the ethics committee of the Hospital Universitario Puerta de Hierro, Majadahonda, Madrid.

Informed Consent Informed consent has been obtained from all patients in this study.

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