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Let's talk about sexuality: SEXual SATisfaction questionnaire in patients with Metastatic breast cancer (SEXSAT-M)

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Background

Breast cancer (BC) treatments can produce changes in patients that affect their identity, attractiveness, self-esteem, social relationships, and sexual functioning [1]. Sexual concerns are reported by 50 to 80% of patients with a diagnosis of metastatic BC (MBC) and patients would like assistance in addressing treatment-related sexual issues [2].

A Spanish study developed and validated the "SEXual SATisfaction Questionnaire" (SEXSAT-Q), that is capable of measuring sexual satisfaction in early BC [3]. However, it fails to cover critical aspects of MBC.

For this reason, a group of Spanish hospitals has adapted and validated a new version to measure sexual satisfaction in MBC (**SEX**ual **SAT**isfaction questionnaire in patients with **M**etastatic breast cancer, **SEXSAT-M**).

Methods

- This is an **observational, cross-sectional, multicenter study** conducted in 12 oncologic hospitals in Spain under conditions of routine clinical practice. This study was approved by Reference Research Ethics Committee (RREC from University Hospitals *Virgen Macarena* and *Virgen del Rocío*), and all participants gave their informed consent.

- **Phases:**

1) A focus group was conducted with 6 patients to assess concept relevance and extract the most relevant contents of the previous questionnaire.

2) A sample of 23 patients was recruited at a single center to pilot the first version for language comprehension.

3) A sample of 223 patients was recruited at 12 oncologic hospitals in Spain to validate the new questionnaire.

4) A retest sample (58 patients) was used to check time stability.

- The **validation of the questionnaire was done by patients** recruited according to:

Inclusion criteria
– Outpatients, female, diagnosed with metastatic breast cancer
– ≥ 25 years old
– ECOG 0-1
– Active sexual life at least 6 months before the diagnosis of advanced disease
– Receiving treatment for advanced disease
– Able to understand and respond to the questionnaire
– Give informed consent
Exclusion criteria
– Not sexually active at least 6 months prior to treatment for their disease
– Early-stage breast cancer
– All those patients who do not meet the inclusion criteria

- **The principal variable was the patients' satisfaction with their sexual life.** Patient satisfaction is structured in four related dimensions: (i) sexual activity (level of sexual activity, interest in sexual activity, discomfort, libido, and satisfaction with sexual activity); (ii) self-image; (iii) psychological state (depression-energy); and (iv) medical care.

- **Secondary variables** included Visual Analogical Scale (VAS) of Perceived Health Status, Quality of Life (SF-12), and Quality of Life in Cancer Questionnaire (EORTC QLQ- BR23).

- **The self-administered questionnaire SEXSAT-M (Table A)** comprised 18 items plus 3 bolt-on items from the QLQ-BR23 questionnaire referring to sexual activity in the last month. Questions are scored using a 5-point Likert scale.

No, not at all	A Little	Moderate	Quite a bit	Yes, a lot
0	1	2	3	4

- **To assess the psychometric properties of the questionnaire**, feasibility, reliability, content validity, construct validity, and concurrent validity were gauged.

Results

Table A. Sexual Satisfaction Questionnaire

Question	Sexual activity	Self image	Psychological state	Medical care
1. Prior to the diagnosis of my disease, my sexual relations were satisfactory.	●			
2. Since I was diagnosed with metastasis, I feel distressed and anxious.			●	
3. Since starting treatment, I feel sad and depressed.			●	
4. I am afraid that, during love play, my partner's caresses and hugs will hurt me.	●			
5. Sexual intercourse is uncomfortable and/or painful for me because of vaginal dryness.	●			
6. I feel more tired and do not feel like doing as many things as I did before the disease.			●	
7. The changes undergone during the treatment of the disease make me ashamed to show my body.		●		
8. Since I started the treatment, I find it hard to look at myself in the mirror and accept myself as I am now.		●		
9. I think that the treatment has significantly worsened my body image.		●		
10. During the treatment of my disease my sexual relations have been and are satisfactory.	●			
11. My sexual life has taken a back a secondary place as a result of my disease.	●			
12. Since I was diagnosed with metastasis, my sexual desire has diminished.	●			
13. Since the diagnosis of metastasis, it is more difficult for me to have an orgasm.	●			
14. At the present time, my sexual relations are satisfactory.	●			
15. I trust my doctor to discuss my sexuality problems.				●
16. My doctor has informed me about the impact that my disease can have on my sexuality.				●
17. I think that it is appropriate to discuss issues of my sexuality with my oncologist.				●
18. I believe that sexuality is an important part of me as a person.	●			
19. To what extent were you interested in sex? (*)	●			
20. To what extent did you have an active sex life (with or without intercourse)? (*)	●			
21. Answer this question only if you were sexually active: To what extent did you enjoy sex? (*)	●			

(*) The last three questions refer to sexual activity in the last month.

Table B. Characteristics of the patients included in the study

Variable	Pilot sample (n = 23)	Validation sample (n = 223)
Age, median years (min-max)	51 (40-67)	49 (30-76)
Menopausal status • Post-menopausal, n (%) • Pre/peri-menopausal, n (%) • Unknown	 14 (60.9%) 8 (34.8%) 1 (4.3%)	 76 (34.1%) 147 (65.9%)
Duration of disease from onset, median years (min-max)	1.8 (0.33-8.84)	6.5 (0.13-31.10)
Time from onset to metastasis diagnosis, median years (min-max)	-	2.45 (0.00-25.07) n = 222
Immunohistochemical profile, n (%) • HR+ • HR- • Unknown	 19 (82.6%) 4 (17.4%) 0 (0%)	 177 (79.4%) 37 (16.6%) 9 (4.0%)
• HER 2+ • HER 2-	12 (52.2%) 11 (47.8%)	85 (38.1%) 138 (61.9%)
• HR-/HER2- • HR-/HER2+ • HR+/HER2- • HR+/HER2+ • HR unknown/HER2- • HR unknown/HER2+	1 (4.3%) 3 (13.3%) 10 (43.5%) 9 (39.1%) - -	16 (7.2%) 21 (9.4%) 115 (51.6%) 62 (27.8%) 7 (3.1%) 2 (0.9%)

HR: hormonal receptor; HER 2: human epidermal growth factor receptor 2.

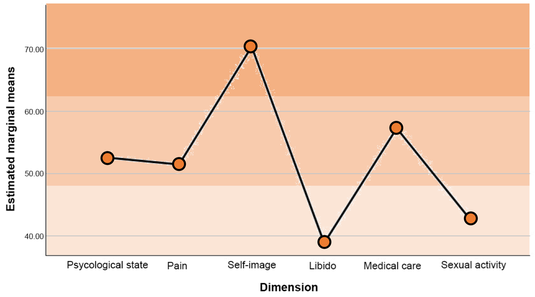


Figure 1. Mean scores in each dimension

- **Focus group** participants corroborated the need to assess the impact of the disease on sexual life.
- The **pilot sample** (the clinical variables of these patients are shown in **Table B**) was able to answer all questions with little or no effort, and 77.3% answered the complete questionnaire, yielding a mean response time of 7.4 minutes (standard deviation 3.9 minutes). One item had to be reverted for better understanding (Question 17).
- Regarding the **validation sample** (The clinical variables of these patients are shown in **Table B**)**:** 227 female patients were recruited, but the case report form (CRF) was not received from 4 patients, resulting in an effective sample of 223 patients. Questionnaires from 219 patients were included in the analysis.
  - 59% responded to all questions, while full completion rate rises to 87.7% when the 3 bolt-on questions are not considered. Question 21 has the higher blank response rate (33.3%).
  - It was found that 75% of the patients with a retest who left question 21 blank in the initial test also left it blank in the retest. Moreover, those who did respond in the retest generally gave low scores.
  - Using the information from the 10-point VAS that asks about overall satisfaction with sexual relations, the score was compared between the group that responded and the group that did not. The mean score for the responding group was 5.46, while the mean for the non-responding group was 1.56. The difference was statistically significant ($p < 0.001$), indicating lower satisfaction among those who did not respond.
- The dimension scores (and the overall score) have been rescaled to a common metric, with a minimum of 0 and a maximum of 100 points. A patient's score can be interpreted based on the percentile in the distribution occupied by the direct score obtained.
- **Dimension (mean) scores** resulted to arrange in three distinguishable levels (**Figure 1**):
  - Self-image (70.3) at the highest level.
  - Pain (51.4), Psychological State (52.5) and Medical Care (57.2) at an intermediate level.
  - Libido (38.8) and Sexual Activity (42.8) located at the lowest level.
- Self-image shows a significantly higher mean than all other dimensions ($p < 0.001$); libido and sexual activity show a significantly lower mean than all other dimensions ($p < 0.001$); psychological state, pain, and medical care do not differ from each other ($p > 0.05$).

Conclusions

- The SEXSAT-M questionnaire was very well accepted and easy to complete by almost all patients, proving good face value and acceptance.
- We consider question 21 may also be left blank by healthy women, possibly due to the nuance involved in qualifying the relationships as "satisfying" (possible cultural bias).
- This new tool can help assess sexual satisfaction in the MBC population with the aim of improving sexual health at this stage of the disease.
- Our instrument gives the opportunity to expose a very sensitive content which MBC women have mentioned to be an important part of their lives, and which is seldom explored in regular practice.

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