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ORIGINAL ARTICLE

UNMET NEEDS AMONG BREAST CANCER PATIENTS IN A DEVELOPING COUNTRY AND SUPPORTIVE CARE NEEDS SURVEY VALIDATION

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ABSTRACT

Background: Identifying and addressing breast cancer (BC) patients' unmet needs (UN) are crucial due to their possible contribution to higher levels of morbidity, particularly in vulnerable underserved populations, such as Latinas with BC. **Objective:** This study aimed to (1) identify and describe the most frequently reported items of moderate-high UN among Mexican women with BC covered by public healthcare insurance; (2) analyze the differences in UN domains according to participants' sociodemographic and clinical characteristics; and (3) validate the Supportive Care Needs Survey-Short Form-34 (SCNS-SF34). **Methods:** A cross-sectional study was conducted with 396 consecutive BC patients. A linguistically translated and culturally adapted version of the SCNS-SF34 for Mexican women with BC was completed by the participants. **Results:** The validation yielded a 32-item version of the SCNS with adequate psychometric properties. The Health System and Providers Information was the highest UN domain, followed by the psychological domain. "Fears about cancer spreading" (37.4%) and "Concerns about the worries of those close to you" (37.3%) were the most prevalent moderate-high UN. Sexuality was the only domain associated with clinical and sociodemographic characteristics. **Conclusion:** By defining the most urgent needs of this group of patients, our results will enable the development of targeted support services and patient-centered care. (REV INVEST CLIN. [AHEAD OF PRINT])

Key words: Breast cancer. Needs assessment. Unmet needs. Mexico.

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INTRODUCTION

It is well known that the diagnosis and treatment of breast cancer (BC) have not only physical but also social, psychological, and spiritual consequences that give rise to supportive care needs (SCN) among patients[1]. In limited-resource settings, like the Mexican public health-care systems cancer care is predominantly focused on providing oncological treatment, bypassing survivorship issues, and supportive care. Thus, the SCN of BC patients are not systematically evaluated or addressed, generating unmet needs (UN) between the services that patients require and the actual care that they receive[2,3].

Identifying and addressing BC patients' UN – the gap between patients' experience and their requirements – is crucial due to their likely contribution to higher levels of morbidity and impaired transition toward the survivorship phase[4], particularly in vulnerable underserved populations, such as Latinas with BC, whose low income has been correlated with more UN[5]. The characterization of patients' UN is possible through the use of accurate measures such as the SCN Survey-Short Form-34 (SCNS-SF34), which has been identified as one of the most comprehensive and psychometrically robust cancer-specific tools for assessing SCN[6,7].

A Mexican version of the SCNS-SF34 was previously validated with a mixed sample of cancer patients[8]. However, several variables may affect the psychometric properties of an instrument, including the patient population and cross-cultural issues. Therefore, our group developed a culturally adapted and linguistically translated version of the SCNS-SF34 exclusively for Mexican BC patients[9]. Nevertheless, its psychometric properties were not yet evaluated. The availability of an appropriately adapted, translated, and validated instrument in the detection of UN among Mexican patients with BC is a primordial step to enable the generation of accurate information and to promote the development of useful supportive care services for this population[6].

In Mexico, until December 2019, approximately 7,328 women with BC rely on the Popular Insurance (Seguro Popular [SP]) program, a major governmental health reform that enabled the most disadvantaged groups to access defined health-care services for certain diseases, including cancer[10]. Since this program mainly covered costs related to medical treatment, it is likely that BC patients receiving care under SP coverage have SCN which should be identified to deliver appropriate interventions to improve their care, treatment results, and quality of life[11]. Therefore, this study aimed to identify and describe the UN most frequently reported by BC patients covered by SP, analyze differences in UN according to sociodemographic and clinical characteristics, and validate the SCNS-SF34 among Mexican women with BC.

METHODS

Participants

Consecutive patients diagnosed with BC, ≥18 years, treated at the National Cancer Institute (Instituto Nacional de Cancerología [INCan]) in Mexico City, and covered through SP were eligible. Exclusion criteria were refusal to participate and the presence of repeated data or incomplete answers to the survey's questions.

From June 2015 to August 2016, 450 BC patients were invited to participate. Of these, 396 consented, 40 (10%) refused by referring that they did not have time or interest in participating, and 14 (3%) were excluded due to inaccuracies in data recording not related to patients' acceptability. Of note, in a previous report that assessed the cultural adaptation of the SCNS-SF34, patients stated that they felt comfortable with all the survey's items[9].

Patients' mean age was 49 years (SD = 11.2) and mean time since diagnosis was 34 months (SD = 37). In total, 70% had completed middle-high school education, 62% were unemployed, and 91% belonged to a low socioeconomic level. Most patients were not their household's main financial provider. The most frequent BC clinical stages were III-IV. Most participants had already started cancer therapy and were receiving active treatment at the time of the survey (Supplemental Table 1).

Instrument

The SCNS-SF34 measures cancer patients' perceptions of SCN across five domains: psychological, health system and information, physical and daily living (PDL), patient care and support (PCS), and sexuality. Patients indicate their need for help over the past month as a result of having cancer on a 5-point Likert scale with the following response options: 1 = no need, not applicable; 2 = no need, satisfied; 3 = low need; 4 = moderate need; and 5 = high need. A standardized domain score ranging from 0 to 100 can then be calculated, with higher scores reflecting greater levels of UN. In the original validation study, the five factors accounted for 72.1% of the total variance, and the internal reliability coefficients exceeded 0.8 for all domains[6]. This study used the linguistically translated and culturally adapted SCNS-SF34 version for Mexican BC patients[9]. Clinical and sociodemographic characteristics were obtained from participants' clinical records.

Procedure

In this cross-sectional study, potentially eligible patients were identified and given a verbal explanation of the study's objectives and data confidentiality. All those who agreed to participate provided their written informed consent. To maximize standardization, the SCNS-SF34 was completed by a trained research psychologist through a face-to-face interview in a private office[8]. Participants' responses for each item of the survey were recorded. All personal data were kept private and confidential. This study was approved by the Ethics and Research Review Board of INCan.

Statistical Analysis

Psychometric evaluation of SCNS-SF34

Four analyses were performed[12]: (1) item discrimination was assessed with the Mann–Whitney U-test ($p < 0.05$); (2) Cronbach's alpha coefficient evaluated the scale's reliability; (3) factorial validity was evaluated using principal components factor analysis with the criteria for factorial validity[13]; and (4) confirmatory factor analyses (CFAs) to empirically explore the factor structures shown in the exploratory factor analysis (EFA). The sample size was calculated based on five patients for each of the original survey's 34 items[12].

Prevalence and correlates of UN

A standardized Likert summated score was calculated for each domain to identify those of highest and lowest UN[14]. The most prevalent UN were identified by calculating the percentage of patients that endorsed each item at a moderate-high level. The Mann–Whitney U-test was used to compare differences between domains by sociodemographic and clinical variables. A two-tailed $p < 0.05$ was considered significant. Statistical procedures were conducted using SPSS 22 J.

RESULTS

Internal Structure and Psychometric Evidence

According to EFA, using principal components analysis with Varimax rotation, Bartlett's test statistic for the significance of the correlation matrix was appropriate (7,379.601, p = 0.0001). Sample adequacy was confirmed by the Kaiser-Meyer-Olkin statistic of 0.922. The factor analysis resulted in a three-factor solution (health system and providers and information [HSPI], psychological, and PDL), and two indicators comprised less than 3 items each (sexuality and PCS choice [PCSCh]). This version obtained 32 items, which accounted for 60.1% of the total variance (Supplemental Tables 2 and 3).

The model obtained by the CFA showed good adjustment, as indicated by the following values: CMIN/df = 1.987, p = 0.000; NFI = 0.883; GFI = 0.874; CFI = 0.938; and RMSEA = 0.05, with a 95% confidence interval between 0.045 and 0.055. The resulting SCNS-SF32 for Mexican BC patients demonstrated satisfactory internal consistency, with Cronbach's alpha of 0.70. Cronbach's alphas for the domains were ranged 0.94-0.75 (Supplemental Table 3).

Prevalence and Correlates of UN

Based on the factor structure found in this study, UN were highest in the HSPI domain, followed by psychological and PDL. In contrast, UN were lowest in the PCSCh domain (Supplemental Table 4). The two main items rated as moderate-high UN were "Fears about the cancer spreading" and "Concerns about the worries of those close to you." Women with ≤12 months since diagnosis reported significantly more HSPI needs ($p = 0.02$) than those with >12 months. Sexuality needs were significantly different according to several sociodemographic and clinical characteristics. Patients who reported more sexuality UN were <50 years ($p = 0.007$); married ($p \leq 0.0001$); had middle-high school education ($p = 0.0452$); their BC treatment was sponsored by others (not by themselves) ($p = 0.021$); and had already undergone chemotherapy ($p = 0.03$) or were on active treatment ($p = 0.02$) (Supplemental Table 1).

DISCUSSION

This validation's explained variance was acceptable, as has been argued in other studies with similar versions (among other BC patients) and with consistent results[6,15-17]. Although our construct validity was lower than that of the Japanese version, it was superior to the Chinese adaptation and the Mexican version for cancer patients in general[8,15-17]. Of note, other authors have previously proposed that the size of variance might be influenced by other cancer-specific needs which are not evaluated in this more general instrument[15]. Furthermore, the reliability coefficient of the present validation was similar to those reported in the original and the Mexican, French, Japanese, Chinese and earlier versions[6,8,15-17].

At the domain level, HSPI exhibited the highest UN. This finding is consistent with those reported in other studies with young Mexican women, Chinese, and low-income Latinas with BC[5,15,18,24]. Patients' lack of information might be partially explained by the existence of barriers to access information and inadequate patient-physician communication[3]. Given that the main UN is related to information, our research group has dedicated efforts to develop materials that can be used by Spanish-speaking patients, and we are assessing their impact on the needs[19].

Opposingly, our study found that PCSCh UN were the lowest. This contrasts with other studies evaluating Mexican cancer patients and young women with BC which reported sexuality as the domain of the lowest need[8,24]. The different phases of the cancer trajectory in which each sample was, might be correlated to these discrepancies between studies[1]. In the present study, as well as in the study evaluating young Mexican women, most patients already received or were receiving active treatment and might, therefore, be more concerned about their medical team choices and treatment recommendations, which explains why information needs are the most unsatisfied[24].

This study also found that patients with ≤12 months since diagnosis had higher HSPI scores than those with >12 months. These results are consistent with those observed in other Mexican patients[18] and confirm that recently diagnosed cancer patients have greater information needs than those in later phases of treatment or survivorship[20]. As previously reported, a recent BC diagnosis poses physical, emotional, social, psychological, and informational challenges that require patients to seek and learn new skills, and to reach out to other people to meet these new needs[1].

Interestingly, sexuality was the only domain associated with clinical and sociodemographic characteristics. Being younger and receiving chemotherapies were associated with higher levels of sexuality needs. In line with this observation, other studies have described that sexual dysfunction is especially prominent among young women, who are more vulnerable to chemotherapy-related changes in ovarian function[21]. The association between having a partner and higher sexuality UN has also been previously described and could be related to the changes and repercussions of a cancer diagnosis on intimate relationships with active sexual lives[2,8,11,18]. Likewise, not being the household's main financial provider and having a higher schooling were also associated with higher sexuality needs[8], but their specific causes have not been elucidated.

At the item level, "Fears about cancer spreading" and "Concerns about the worries of those close to you" were the most frequently reported moderate-high UN, which is consistent with several studies among low-income Latinas and young Mexican BC patients, as well as with Japanese, German, and French women with BC[5,16,17,24], rural populations[6], among others. These findings could reflect the magnitude of the psychological impact associated with recurrence (regardless of stage), treatment trajectory, culture, or other sociodemographic variables[7]. Concerning the fear of recurrence UN, we are culturally adapting interventions, which have shown to be effective[22], and consequently exploring their effectiveness.

This study has some limitations that should be considered. Mainly, these results correspond to BC patients from a single Mexican health care institution. However, it is important to point out it represents the main cancer referral center in the country and receives BC patients from several states. Likewise, the study only included patients with governmental health-care insurance. Nonetheless, these findings could be applicable to other Mexican contexts and Latin American countries as nearly half of the population is covered by similar public health-care systems[23]. Another limitation of this study is related to the unfeasible self-administration of the survey due to participants' low literacy levels[8], and applying the survey through face-to-face interviews may have led to social desirability response bias.

In conclusion, this study showed that the culturally adapted and linguistically translated SCNS-SF32 for Mexican BC patients has good psychometric properties and is paramount for the identification of their most pressing needs. Moreover, due to the urgency of recognizing and providing supportive care to this population, the availability of the first version in Spanish specifically for BC patients is of utmost importance as it represents a valuable tool and model for other Spanish-speaking countries, which lack validated versions specific to their populations.

Furthermore, this study is the first to explore the SCN of disadvantaged BC patients in Latin America. Given that the assessment of SCN is a crucial step in the development and delivery of appropriate interventions that can improve BC patients' quality of life, the SCNS-SF32 will enable a better understanding of the services that should be provided to these patients and optimize the care provided by health-care systems. Our findings suggest that supportive care mainly targeting these patients' needs related to the health-care system, providers, and information delivery, especially among those who are more recently diagnosed, is a priority to develop directed support services and offer patient-centered care.

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SUPPLEMENTARY DATA

Supplementary data are available at Revista de Investigación Clínica online (www.clinicalandtranslationalinvestigation.com). These data are provided by the corresponding author and published online for the benefit of the reader. The contents of supplementary data are the sole responsibility of the authors.

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ORIGINAL ARTICLE

Unmet Needs Among Breast Cancer Patients in a Developing Country and Supportive Care Needs Survey Validation

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Table S1. Demographic and clinical characteristics and analysis by needs domain (n = 396)

Demographic and clinical variables	All	Health system and providers, and information	Psychological	PDL	PCS choice	Sexuality
	Number (%)	M (Me, IQR)				
Total	396 (100)	38 (29, 28)	35 (30, 43)	35 (30, 40)	16 (0, 25)	23 (0,50)
Age M (Me, *IQR*)	49 (49, 16)					
≤40	96 (33)	39 (27, 32)	35 (29, 35)	36 (35,35)	16 (0,25)	29 (0, 50)**
>50	191 (66)	35 (27, 23)	32 (28, 37)	33 (30,40)	12 (0, 12)	17 (0, 25)**
Time (months) since diagnosis M (Me, IQR)	34 (16, 45)					
≤12	174 (44)	42 (30, 38)*	37 (32,42)	36 (30, 40)	16 (0, 25)	22 (0, 50)
>12	222 (56)	35 (26, 21)*	34 (29, 40)	34 (30, 35)	16 (0, 25)	24 (0, 50)
Marital status						
Single	186 (47)	38 (30, 26)	36 (27, 40)	34 (35, 40)	16 (0, 25)	14 (0, 0)**
Married	210 (53)	38 (25, 29)	35 (32, 40)	35 (30, 40)	16 (0, 25)	31 (0, 50)**
Education level[a]						
Low	119 (30)	35 (27, 44)	35 (30, 47)	35 (35, 40)	13 (0, 25)	18 (0, 25)*
Middle-high	277 (70)	39 (29, 33)	35 (30, 40)	35 (30, 40)	17 (0, 25)	25 (0, 50)*
Household's main financial provider						
Patient	91 (23)	39 (29, 26)	39 (35, 40)	35 (30, 35)	16 (0, 25)	16 (0, 12)*
Other	305 (77)	38 (27, 29)	34 (30, 38)	35 (30, 40)	16 (0, 25)	26 (0, 50)*
Treatment[b]						
Chemotherapy						
Yes	282 (71)	38 (29, 28)	35 (30, 38)	35 (30, 40)	16 (0, 25)	24 (0, 50)*
No		39 (28, 32)	41 (35, 54)	35 (32, 43)	17 (0, 25)	13 (0, 12)*
Medical status						
Active treatment (including palliative care)	258 (65)	39 (29, 17)	35 (30, 38)	34 (30, 40)	17 (0, 25)	26 (0, 50)*
Survivorship	138 (35)	37 (27, 27)	37 (34, 40)	37 (40, 40)	15 (0, 25)	19 (0, 25)*

Data are categorized by the factor structure/domains which emerged in this study as the Mexican SCNS-SF32 for BC.
*Significance by Mann–Whitney U-test $p < 0.5$.
**< 0.0001.
[a]Low (none, elementary school); middle (secondary and high school); high (university or higher).
[b]Multiple responses were allowed per participant.
M: mean; Me: median; IQR: interquartile range. PDL: physical and daily living, PCS: patient care and support.

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Table S2. Principal components factor analysis of the SCNS-SF34 (Varimax rotation) (n = 396)

Item number and item		HSPI	Ps	PDL	Sexuality	PCSch
		1	2	3	4	5
29	Being informed about the things you can do to help yourself get well	0.81	0.162	0.077	0.03	−0.032
26	Being adequately informed about the benefits and side effects of treatments before you choose to have them	0.795	0.179	0.117	0.052	0.086
27	Being informed about your test results as soon as feasible	0.782	0.198	0.077	0.025	0.093
34	Having a hospital staff member with whom you can talk to about all aspects of your condition, treatment, and follow-up	0.776	0.171	0.093	0.047	0.123
25	Being given explanations of those tests for which you would like explanations	0.774	0.201	0.108	0.096	0.158
32	Being treated like a person, not just another case	0.77	0.176	0.193	0.058	0.207
28	Being informed about cancer which is under control or diminishing (that is, remission)	0.77	0.211	0.08	0.026	−0.074
24	Being given information (written, diagrams, drawings) about aspects of managing your illness and side effects at home	0.728	0.115	0.17	0.038	0.161
23	Being given written information about the important aspects of your care	0.707	0.133	0.227	0.043	0.235
30	Having access to professional counseling (e.g., psychologist, social worker, counselor, and nurse specialist) if you, your family or friends need it	0.696	0.223	−0.075	0.054	0.08
33	Being treated in a hospital or clinic that is as physically pleasant as possible	0.638	0.117	0.129	0.035	−0.013
22	Hospital staff acknowledging and showing sensitivity to your feelings and emotional needs	0.574	0.21	0.185	0.156	0.295
21	Hospital staff attending promptly to your physical needs	0.522	0.135	0.144	0.131	0.321
10	Worry that the results of treatment are beyond your control	0.157	0.772	0.068	0.066	0.179
9	Fears about cancer spreading	0.167	0.766	0.062	0.035	0.096
11	Uncertainty about the future	0.235	0.752	0.021	0.051	0.148
14	Feelings about death and dying	0.133	0.7	0.033	0.24	0.128
8	Feeling of sadness	0.214	0.661	0.359	0.029	−0.155
7	Feeling down or depressed	0.166	0.66	0.372	0.019	−0.189
12	Learning to feel in control of your situation	0.311	0.617	0.125	0.2	0.128
17	Concerns about the worries of those close to you	0.275	0.585	0.315	−0.016	0.04
13	Keeping a positive outlook	0.14	0.542	0.246	0.238	0.059
6	Anxiety	0.304	0.469	0.366	0.003	-0.18
2	Lack of energy/tiredness	0.116	0.142	0.722	0.044	0.035
3	Feeling unwell a lot of the time	0.106	0.212	0.691	0.077	0.169
5	Not being able to do the things you used to do	0.018	0.12	0.64	0.009	−0.085
4	Work around the home	0.168	0.098	0.632	0.156	0.056
1	Pain	0.02	0.124	0.623	0.009	0.114
16	Changes in your sexual relationships	0.122	0.182	0.146	0.909	0.012
15	Changes in sexual feelings	0.101	0.246	0.09	0.894	0.045
18	More choices about which cancer specialist you see	0.308	0.13	0.105	0.01	0.766
19	More choices about which hospital you attend	0.269	0.081	0.062	0.027	0.716
*20	Reassurance by medical staff that the way you feel is normal	0.412	0.102	0.195	−0.073	0.440
*31	Being given information about sexual relationships	0.555	0.171	0.026	0.437	−0.037

Loadings in bold represent patterns for each factor.
*Removed items.
HSPI: health system and providers and information; Ps: psychological; PDL: physical and daily living; PCSch: patient care and support choice.

Table S3. Psychometric properties of the final SCNS-SF 32 Mexican breast cancer

Factors	Mean[a] (SD)	Variance (%)	Cronbach's alpha	Hotelling's T^2	p-value
Factor 1 (HSPI)	38.38 (24.90)	23.65	0.94	112.79	<0.001
Factor 2 (Ps)	35.51 (26.76)	15.53	0.9	174.9	<0.001
Factor 3 (PDL)	35.32 (25.65)	9.60	0.75	95.28	<0.001
Indicator 1 (Sexuality)	23.45 (35.31)	5.90	0.9	0.784	0.377
Indicator 2 (PCSCh)	16.31 (27.94)	5.40	0.91	4.855	0.028
Total		60.11	0.94	541.75	

*Significance was obtained by Mann–Whitney U-test <0.5; <0.0001.

[a] Standardized Likert summated scores. A higher score represents higher levels of UN.

HSPI: health system and providers and information; Ps: psychological; PDL: physical and daily living; PCSCh: patient care and support choice.

Table S4. Prevalence of moderate-high UN

Rank	Item	%	Domain
1	Fears about the cancer spreading	37.4	Ps
2	Concerns about the worries of those close to you	37.3	Ps
3	Lack of energy/tiredness	34.3	PDL
4	Uncertainty about the future	33.8	Ps
5	Not being able to do the things you used to do	32.8	PDL
6	Being informed about things you can do to help yourself get well	32.8	HSPI
7	Being informed about cancer which is under control or diminishing (that is, remission)	31.8	HSPI
8	Having a hospital staff member with whom you can talk to about all aspects of your condition, treatment, and follow-up	28.8	PCSch
9	Being informed about your test results as soon as feasible	28	HSPI
10	Work around the home	27	PDL

HSPI: health system and providers and information; Ps: psychological; PDL: physical and daily living; PCSCh: patient care and support choice.

DESCRIPTIONS AND ANALYSIS OF INTERNAL STRUCTURE AND PSYCHOMETRIC EVIDENCE BY FACTORS

The factor analysis resulted in a three-factor solution and two indicators comprised less than 3 items each. Factor 1 accounted for 23.7% of the variance and comprised 13 items that addressed needs concerning healthcare providers and the treatment center, as well as information on the disease, diagnosis, treatment, and follow-up. Therefore, Factor 1 was labeled "Health System and Providers, and Information (HSPI)."

Factor 2 accounted for 15.5% of the variance and consisted of 10 items regarding emotions and coping needs, and was labeled "Psychological." Factor 3 accounted for 9.6% of the variance, comprised five items related to coping with physical symptoms, treatment side effects, and performing usual tasks and activities, and was labeled "Physical and Daily Living (PDL)." Indicator 1 accounted for 5.9% of the variance, encompassed two items regarding sexual relationships, and was labeled "Sexuality." Finally, Indicator 2 accounted for 5.4% of the variance, consisted of two items reflecting needs about health-care (providers and centers) choice, and was labeled "Patient Care and Support Choice (PCSCh)."

In our 32-item solution, HSPI was the largest domain because it included items of the original PCS domain, similarly to the Chinese version[1]. A possible explanation could be that our sample perceived all items related to healthcare providers as part of the health system. In contrast, the items encompassed in the psychological and PDL factors in our 32-item solution were compatible with the original version[2].

Indicator 1 (sexuality) comprised two items regarding changes in sexuality and did not include item 31, related to sexual information. This result is consistent with the Mexican version validated among cancer patients in general[3]. A possible reason is that BC patients may perceive that receiving sexuality-related information is not directly associated to their sexual life circumstances. Indicator 2 (PCSCh) included two items related to choosing cancer care hospitals and specialists but removed item 20, "Reassurance by medical staff that the way you feel is normal." Given that this outcome differs from other versions of the instrument, it suggests that our sample may not perceive comfort and emotional support as a predominant role of the medical staff, and is consistent with the fact that care provided under SP is focused mainly on medical treatment.

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