Assessment of needs, health-related quality of life, and satisfaction with care in breast cancer patients to better target supportive care

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Background: This study assessed whether breast cancer (BC) patients express similar levels of needs for equivalent severity of symptoms, functioning difficulties, or degrees of satisfaction with care aspects. BC patients who did (or not) report needs in spite of similar difficulties were identified among their sociodemographic or clinical characteristics.

Patients and methods: Three hundred and eighty-four (73% response rate) BC patients recruited in ambulatory or surgery hospital services completed the European Organisation for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ)-C30 quality of life [health-related quality of life (HRQOL)], the EORTC IN-PATSAT32 (in-patient) or OUT-PATSAT35 (out-patient) satisfaction with care, and the supportive care needs survey short form 34-item (SCNS-SF34) measures.

Results: HRQOL or satisfaction with care scale scores explained 41%, 45%, 40% and 22% of variance in, respectively, psychological, physical/daily living needs, information/health system, and care/support needs ($P < 0.001$). BC patients' education level, having children, hospital service attendance, and anxiety/depression levels significantly predicted differences in psychological needs relative to corresponding difficulties (adjusted $R^2 = 0.11$). Medical history and anxiety/depression levels significantly predicted differences in information/health system needs relative to degrees of satisfaction with doctors, nurses, or radiotherapy technicians and general satisfaction (adjusted $R^2 = 0.12$). Unmet needs were most prevalent in the psychological domains across hospital services.

Conclusions: Assessment of needs, HRQOL, and satisfaction with care highlights the subgroups of BC patients requiring better supportive care targeting.

Key words: care improvement, HRQOL, satisfaction with care, supportive care needs

introduction

Current clinical practice integrates instruments that provide information about a patient's perception of his/her health status or care management [1]. The concept of 'patient-reported outcomes (PROs)' refers to measures that are directly obtained from the patient him or herself [2]. PROs primarily address symptoms, functional status but also health-related quality of life (HRQOL), and satisfaction with care, in relation to medical drugs or devices [3].

PROs are also considered at institutional level for service planning and monitoring [1, 4]. Among them, supportive care needs assessment tools have been developed in the cancer field to directly weight the patient's wish for supportive care

intervention [5]. Supportive care focuses on patients' physical, functional, and psychosocial needs, and acknowledges the importance of the relational and communicational aspects of care. Attending to the perception of the patient's supportive care needs clarifies where actions or resource allocation are necessary, desirable, or useful, to help patients to overcome their difficulties [6].

The subjective experience of breast cancer (BC) is of particular concern, since it entails a traumatic diagnosis for women at all ages and involves lengthy and complex care [7], susceptible to hamper treatment adherence [8]. This makes it crucial to provide appropriate supportive care for these women. The purpose of this study was to assess the supportive care needs of BC patients in relation to their difficulties as they attend hospital services to undergo active treatment.

HRQOL, satisfaction with care, and health-care needs (needs) cover distinct domains [5]. Fung and Hays [4] suggest

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that assessing baseline HRQOL can help identifying a problem; then a needs' assessment helps decide on appropriate action.

HRQOL tools shed light on the intensity of patients' difficulties as a result of disease and treatment across several domains ranging from their symptoms and physical functioning, to cognitive and psychosocial concerns [9]. Satisfaction with care questionnaires offer insights into how the patient perceives the quality of health-care aspects and highlights factors underlying the link between the process of care and its resulting outcome [10]. For example, patients' reports about care (e.g. having received information on services available and useful in a sensitive manner) may be related to HRQOL and satisfaction with care.

Adapted from Fung and Hays [4] and Royse et al. [11], Figure 1 shows a supportive care programme life cycle for BC under active treatment in oncology hospital services. Problems are identified through HRQOL or satisfaction with care assessments, leading to supportive care needs assessment to pinpoint intervention needs from the patients' perspective, and to the design and implementation of the intervention. Then, an evaluation of the intervention's effectiveness is assessed on resulting outcomes, i.e. HRQOL and satisfaction with care. The present study addresses the upper arrows of the picture, exploring the relationships between HRQOL and satisfaction with aspects of care, and reports of needs for supportive care.

Each of these concepts may be measured by instruments that have proved their acceptability, feasibility, and sound psychometrics on their own. In order to integrate them for institutional care planning or monitoring as appropriate tools, it is also important to determine their specificity and usefulness.

In BC patients, compared with HRQOL [12], needs have only been recently studied using quantitative measures [13]; directly assessing needs may provide information on its own. However, HRQOL data have been shown to predict the needs of BC patients [14–16]. Moreover, these data are often used to

infer the patient's needs and elicit intervention [17, 18], suggesting that an evaluation of HRQOL may suffice in indirectly identifying needs. Yet, a number of studies focusing on the relationship between measures of HRQOL and needs highlight important discordances between these assessments [19] and differential clinical implications from the data they elicit [20]. Lower needs related to symptoms or difficulties may imply any of the following: the patient does not expect help with these issues, needs have been or are being met by external services, the patient is not burdened by these difficulties, or there has been an appropriate or sufficient response to need [19].

Satisfaction with care theoretically implies fulfillment of expectations [21], and these may be affected by the nature, number, or seriousness of the patient's health needs [22]. The link between satisfaction with care and needs for care has rarely been empirically tested [23]. Hospital services dissatisfaction has been related to BC patients' unmet health system and information needs [14]. Lower needs relative to similar levels of satisfaction with care may be explained by patients' lower expectations or wishes for specific services [24], lack of knowledge of whether or how specific, efficient care may be accessed [25], and variations in health-care needs at different times along the cancer trajectory [26, 27].

Hence, to help interpret the information provided by needs' assessment in relation to HRQOL (i.e. degree of perceived symptoms or functioning difficulties) or satisfaction with care (i.e. perceptions of aspects of care quality) data, and to highlight supportive care targets, we addressed the following research questions:

(i) To what extent BC patients who report symptoms or functioning difficulties [European Organisation for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ)-C30] or dissatisfaction with care aspects [OUT-PATSAT35 (out-patient)/EORTC
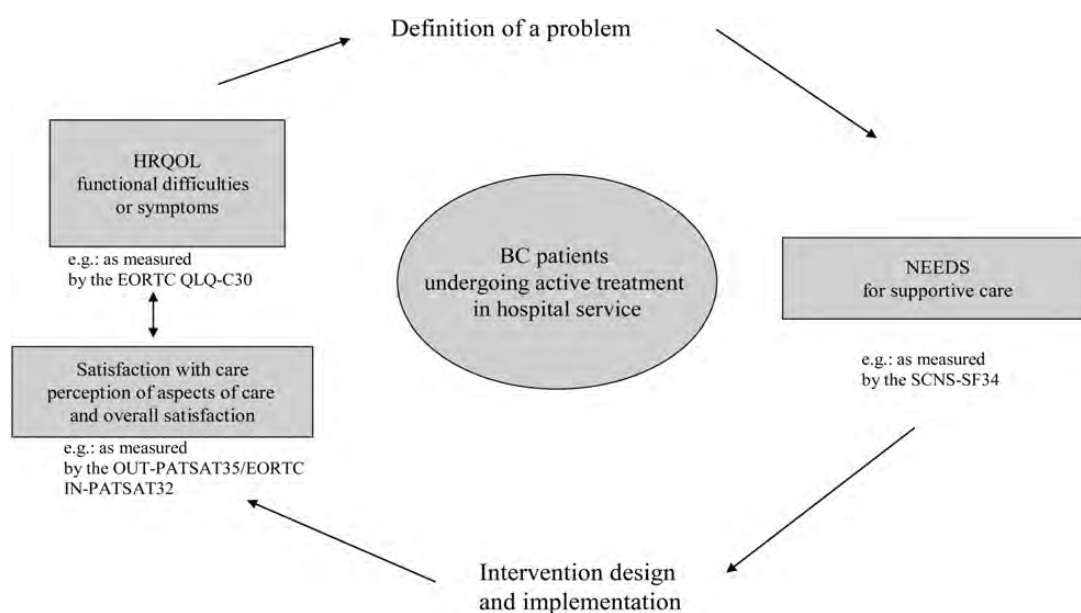
Figure 1. Supportive care intervention programme life cycle proposal for BC under active treatment in oncology hospital services.

IN-PATSAT32 (in patient)] express needs for supportive care [supportive care needs survey- short form 34-item (SCNS-SF34)]?

(ii) Which sociodemographic and clinical factors characterize BC patients who express needs for supportive care compared with those who do not, although they experience similar symptoms, functioning difficulties, or dissatisfaction with care aspects?

patients and methods

An ecological observational study was implemented. A consecutive series of BC patients were recruited between April 2010 and March 2011 in the chemotherapy (CT) day hospital and ambulatory radiotherapy (RT) service of Institute Curie (IC) in Paris (France) and of the University Hospital CHUV in Lausanne (Switzerland), as well as in the BC surgery unit of the CHUV. Informed consent and local or national ethical committee approval were obtained.

patients and data collection

Patients had to be diagnosed with BC, be aged 18 years or older, have sufficient knowledge of French, and be mentally fit to complete a questionnaire.

All questionnaires were distributed in hospital, for completion at home within 6 weeks. Sociodemographic data (age, education level, professional status, and having children or not) and clinical data (time since BC diagnosis, disease stage, current ongoing anti-tumor treatment or not, and medical history) were recorded from medical records.

questionnaires

Patients were asked to complete the French versions of the supportive care needs survey, SCNS-SF34 [28]; the core quality of life questionnaire, EORTC QLQ-C30 (version 3.0) [29]; the Hospital Anxiety and Depression Scale, HADS [30]; and the cancer in-patient or out-patient satisfaction questionnaire, EORTC IN-PATSAT32 [31] or OUT-PATSAT35 [32].

The SCNS-SF34 addresses the level of needs in the psychological, information and health system, physical and daily living, patient care and support, and sexuality domains. The psychometric study of the SCNS-SF34 French version confirmed a five multi-item scale structure [33]. The EORTC QLQ-C30 contains scales and items addressing the functional aspects of HRQOL and symptoms that commonly occur in patients with cancer. The EORTC IN-PATSAT32 assesses cancer patients' satisfaction with the quality of the technical and human aspects of care provided by hospital doctors and nurses, as well as aspects of the care organization and hospital environment. The OUT-PATSAT35 is an adapted version of the EORTC IN-PATSAT32 assessing specific aspects of care in the hospital ambulatory setting. Scale scores of the SNCS-SF34, EORTC QLQ-C30, EORTC IN-PATSAT32, and OUT-PATSAT35 are calculated by averaging items within scales and transforming average scores linearly. Scores range from 0 to 100, so that a high score on a functioning scale, overall quality of life, or satisfaction with care scale indicates good functioning, a good level of overall quality of life, or a high satisfaction with care, respectively; inversely, either a high score on a symptom scale or a need scale indicates more severe symptoms, problems, or needs.

The HADS is a 14-item self-report scale developed for the medical patients, assessing anxiety (HAD-A) and depression (HAD-D). Subjects rate the frequency of anxious or depressive symptoms experienced over the past week. The HAD-A and HAD-D scores range from 0 to 21, a higher score indicating more distress. This questionnaire has been validated in French in cancer in-patients [30].

statistical analyses

To answer research question 1, we carried out four multiple regression analyses using the need scales' scores as dependent variables. For the first two regressions, scores of the psychological and physical and daily living need scales were predicted from scores of the quality of life questionnaire subscales addressing the same domains. For the following two regressions, scores of the information and health system and care and support need scales were predicted from scores of the satisfaction with care subscales also addressing the same domains.

For each regression, R^2 (the percentage of score explained variance) indicates whether needs are more or less strongly predicted by either the quality of life or satisfaction with care assessments. R^2 values of 1%, 9%, or 25% represent small, medium, or large effects, respectively [34]. Explanatory variables are characterized by standardized coefficients, indicating the extent to which they contribute to predict need scale scores: standardized regression coefficients of 0.1 were considered small, 0.3 medium, and 0.5 large [34]. As in each analysis, explanatory variables are scales of a questionnaire, they are expected to be highly correlated and so susceptible to multicollinearity and biasing results. To check multicollinearity, for each regression, we computed the variance inflation factor (VIF) estimates [35]; since the VIF was never >5, we concluded in a small multicollinearity, which does not result too significant bias.

To answer research question 2, we assessed differences between needs and symptoms or functioning difficulties (EORTC QLQ-C30) or satisfaction with providers' care or general satisfaction (EORTC IN-PATSAT32/OUT-PATSAT35). These differences were operationalized by regression residuals (i.e.: differences between observed and predicted values by the best combination of explanatory variables). When residuals are close to 0, need scores are almost perfectly predicted by the EORTC QLQ-C30 or IN-PATSAT32/OUT-PATSAT35 scores; when they are positive, observed need scores are greater than those that could be predicted by the EORTC QLQ-C30 or IN-PATSAT32/OUT-PATSAT35 scores; and when they are negative, the reverse is true. These residuals are then used as dependent variables in new regression models aimed at assessing the weight of explanatory variables that were tested among BC patients' sociodemographic (age, education level, professional status, and having children) or clinical (time since diagnosis, stages of disease, medical history, anxiety or depression, and hospital service attended) characteristics. Statistical analyses were carried out using the R software [36].

results

BC women characteristics and compliance

Five hundred and twenty-six BC patients were approached to participate in this study. Of these, 127 (24%) refused to participate and 15 (2.8%) did not provide evaluable forms.

Non-respondents were significantly older and presented more often with a metastatic disease, a longer time since diagnosis, or breast reconstruction ($P < 0.001$) (Table 1). The sociodemographic and clinical characteristics of the sample are detailed in a previous study [22].

BC women self-reported data

Score means of the SCNS-SF34 ranged from 26 (care and support needs) to 39 (psychological needs) (Table 2). On the overall sample, unmet supportive care needs were primarily prevalent in the psychological domain with 50% or above BC patients reporting unmet needs regarding uncertainty about the future, fear about the cancer spreading, information on

Table 1. Sample sociodemographic and clinical characteristics

	Respondents ($N=384$) n (%)	Non-respondents ($N=142$) n (%)
Age (years)*		
Mean (SD)	54.0 (11.3)	57.7 (12.7)
Married/with a partner	237 (61.7)	89 (65.9)
Missing data	0	7
Education		
Up to superior	197 (51.7)	–
Superior or above	184 (48.3)	–
Missing data	3	–
Having children	295 (76.8)	106 (74.6)
Length of time since diagnosis and questionnaire completion (months)		
Median [range]	6.3 [0.5–284.4]	–
Missing data	1	–
Stage of breast cancer*		
Local/regional	310 (80.7)	89 (63.1)
Metastatic	74 (19.3)	52 (36.9)
Missing data	0	1
Hospital service*		
France		
Chemotherapy day hospital	145 (37.8)	104 (73.2)
Ambulatory radiotherapy	103 (26.8)	23 (16.2)
Switzerland		
Chemotherapy day hospital	34 (8.9)	3 (2.1)
Ambulatory radiotherapy	55 (14.3)	7 (4.9)
Surgery	47 (12.2)	5 (3.5)
Mastectomy	121 (31.5)	48 (34.0)
Missing data	0	1
Breast reconstruction (yes) (patients with surgery only) ($n=456$)*	22 (6.7)	19 (15.0)
Missing data	1	2

Significant difference between respondents and non-respondents: *$P < 0.01$ (two-tailed).

Table 2. Self-reported anxiety and depression and supportive care needs mean (standard deviation) scale scores and prevalence of top 10 unmet supportive care needs ($N = 384$)

HADS	
Mean (SD)—% clinical case (score >10)	
Anxiety	7.3 (3.8)—20.5
Depression	5.3 (4.0)—11.3
Supportive care needs mean (SD)	
Psychological needs	38.5 (24.2)
Information and health system	33.4 (19.2)
Care and support	26.2 (17.4)
Physical and daily life needs	34.5 (23.3)
Sexual needs	30.2 (32.4)
Top 10 unmet supportive care	% unmet needs
Uncertainty about the future[a]	64.1
Fears about the cancer spreading[a]	58.9
Being informed about things you can do to help yourself to get well[b]	58.3
Worry that the results of the treatment are beyond your control[a]	56.9
Not being able to do things you used to do[c]	53.8
Learning to feel in control of your situation[a]	53.3
Lack of energy/tiredness[c]	50.1
Anxiety[a]	49.3
Concerns about the worries of those close to you[a]	48.1
Feelings about death and dying[a]	45.7

[a]Psychological needs.
[b]Health system and information needs.
[c]Physical and daily living needs.

what to do to help oneself get well, or worry that the results of treatment are beyond one's control.

Clinical levels of anxiety or depression were observed in 20.5% and 11.3% of the samples, respectively, which reflects higher levels compared with early BC patients pre-RT [37]. Score means of the EORTC QLQ-C30 functioning and global health status scales ranged from 59 (global health status) to 75 (physical and cognitive functioning) and of symptom scales from 11 (nausea and diarrhoea) to 50 (fatigue), which reveals more difficulties or symptoms than reference data for all stages BC patients aged between 50 and 60 years [38]. Score means of the EORTC IN-PATSAT32 or OUT-PATSAT35 ranged from 61 (doctors' availability) to 78 (nurses' interpersonal skills) evidencing higher satisfaction with doctors' information than all cancer patients data [39].

predicting psychological, physical, and daily living needs by BC patients' reported corresponding difficulties

Moderate proportions of variance in the SCNS-SF34 psychological, physical and daily living need scores were explained by EORTC QLQ-C30 corresponding scales (adjusted $R^2 = 0.41$ and 0.45, respectively; $P < 0.001$). Lower emotional functioning only was significantly associated with psychological needs ($\beta = -0.55$). Physical functioning ($\beta = -0.14$), fatigue ($\beta = 0.17$), pain ($\beta = 0.19$), dyspnoea ($\beta = 0.13$), and constipation ($\beta = 0.09$) were significantly associated with physical and daily living needs but not role functioning, global health status, nausea, appetite loss, and diarrhoea (supplementary Table S1, available at Annals of Oncology online).

predicting needs for information and health system, care and support by BC patients' satisfaction with care aspects

The proportions of variance explained in the SCNS-SF34 information and health system, care and support need scales by the EORTC IN-PATSAT32 or OUT-PATSAT35 doctors/ nurses/RT technicians, and general satisfaction scales were moderate (adjusted $R^2 = 0.40$; $P < 0.001$) and small (adjusted $R^2 = 0.22$; $P < 0.001$). Higher satisfaction with doctors' interpersonal skills ($\beta = -0.19$) and information provision ($\beta = -0.37$), and higher general satisfaction ($\beta = -0.15$) were associated with lower information or health system needs. Higher satisfaction with doctors' information provision (($\beta = -0.19$) and higher general satisfaction ($\beta = -0.18$) were associated with lower care and support needs (supplementary Table S2, available at Annals of Oncology online).

BC patients' characteristics explaining higher or lower psychological, physical, and daily living needs for similar level reported difficulties

As reported in Table 3, in multivariate analysis, discrepancies between SCNS-SF34 psychological needs and the EORTC QLQ-C30 corresponding scales were significantly predicted (adjusted $R^2 = 0.11$; $P < 0.001$) by BC patients' education level ($\beta = -0.20$), having children ($\beta = 0.13$), hospital service ($\beta = -0.13$; $\beta = -0.16$), and anxiety ($\beta = 0.15$) or depression ($\beta = 0.13$) levels. BC patients with a superior level of education or attending specific hospital services presented lower levels of psychological needs than expected from their EORTC QLQ-C30 level of emotional, cognitive, social functioning, global health status, fatigue, or sleep difficulties compared with women with a compulsory level of education, whereas BC patients having children or with a higher anxiety or depression level evidenced higher psychological needs than expected from their reported difficulties. However, the multivariate model did

not significantly predict discrepancies between SCNS-SF34 physical and daily living needs and the EORTC QLQ-C30 corresponding scales (adjusted $R^2 = 0.02$).

BC women characteristics explaining higher/lower needs for information and health system, and care and support for similar level satisfaction with doctors, nurses, or radiotherapy technicians' care and general satisfaction

As reported in Table 4, in multivariate analyses, discrepancies between the SCNS-SF34 information and health system need scale scores and scores of the EORTC IN-PATSAT32 or OUT-PATSAT35 doctors/nurses/RT technicians and general satisfaction scales were significantly predicted (adjusted $R^2 = 0.11$; $P < 0.001$) by BC medical history ($\beta = -0.11$), anxiety ($\beta = 0.15$), and depression ($\beta = 0.20$). BC patients who

Table 3. BC women characteristics explaining higher/lower psychological or physical and daily living needs for similar levels of reported difficulties

Factors	Psychological needs and corresponding EORTC QLQ-C30 scale differences	Physical and daily living needs and EORTC QLQ-C30 corresponding scale differences
	β	β
Age	NS	NS
Education level (reference = compulsory)		
Secondary	NS	NS
Technical–professional	NS	NS
Superior	−0.20*	NS
Professional status (working)		
Having children	0.13*	NS
Hospital services (reference = CT-IC)		
RT-IC	NS	−0.16*
CT-CHUV	−0.13*	NS
Surgery-CHUV	−0.16*	NS
RT-CHUV	NS	NS
Time since diagnosis	NS	NS
Metastatic disease	NS	NS
On-treatment	NS	NS
Medical history	NS	NS
HADS-anxiety	0.15*	NS
HADS-depression	0.13*	NS
Adjusted R^2	0.11	0.02
F statistics	3.91***	1.52
df	15,345	15,344

Significant predictors: *$P < 0.05$; ***$P < 0.001$.
NS, non-significant; CT, chemotherapy; RT, radiotherapy; IC, Institute Curie; CHUV, University Hospital Center Vaudois.

Table 4. BC women characteristics explaining higher/lower needs for information and health system, and care and support for similar levels of satisfaction with doctors, nurses, or radiotherapy technicians' care and general satisfaction

Factors	Information and health system needs and corresponding satisfaction with care scale differences	Care and support needs and corresponding satisfaction with care scale differences
	β	β
Age	NS	NS
Education level (reference = compulsory)		
Secondary	NS	NS
Technical–professional	NS	NS
Superior	NS	NS
Professional status (working)	NS	NS
Having children	NS	NS
Hospital services (reference = CT-IC)		
RT-IC	NS	NS
CT-CHUV	NS	0.13*
Surgery-CHUV	NS	NS
RT-CHUV	NS	NS
Time since diagnosis	NS	NS
Metastatic disease	NS	NS
On-treatment	NS	NS
Medical history	−0.11*	NS
HADS-anxiety	0.15*	NS
HADS-depression	0.20**	NS
Adjusted R^2	0.12	0.00
F statistics	3.97***	<1
df	16,337	16, 329

Only significant predictors reported: *$P < 00.05$; **$P < 0.01$; ***$P < 0.001$.
NS, non-significant; CT, chemotherapy; RT, radiotherapy; IC, Institute Curie; CHUV, University Hospital Center Vaudois.

experienced a medical history displayed lower information and health system needs for similar levels of satisfaction with doctors, nurses, or RT technicians and general satisfaction, whereas those who presented higher levels of anxiety or depression manifested higher needs on that scale relatively to their level of satisfaction with care. The multivariate model did not significantly predict discrepancies between the SCNS-SF34 care and support need scale scores and scores of the EORTC IN-PATSAT32 or OUT-PATSAT35 doctors/nurses/RT technicians and general satisfaction scales (adjusted $R^2 = 0.00$).

discussion

In this study, BC patient subgroups expressed supportive care needs, but others did not although experiencing similar levels of symptoms, functioning difficulties, or (dis)satisfaction with care aspects. Indeed, moderate score variation in supportive care needs as measured by the SCNS-SF34 was explained by those EORTC QLQ-C30 scales addressing similar items or domains, and moderate and small score variances in needs for information and health system, or care and support were explained by satisfaction with the care provided by doctors, nurses, or RT technicians and by general satisfaction.

Factors related to BC patients and hospital services explained differences in expressing needs. For example, higher levels of psychological needs for similar levels of emotional difficulties were observed in BC patients with children or those presenting clinical levels of anxiety or depression, which suggests insufficient attention to the needs of these patients. The higher needs of BC patients with clinical levels of distress relative to difficulties revealed by the EORTC QLQ-C30 on psychological domains indicate that the EORTC QLQ-C30 may not be sufficiently sensitive for use as a distress-screening instrument.

BC women with a superior level of education expressed lower needs for psychological help for similar levels of difficulty, which suggests higher self-efficacy in obtaining external services, if necessary, compared with women with a lower level of education. Needs were lower in specific oncology services compared with others for similar levels of symptoms and difficulties implying differences between services in terms of responsiveness to patients' psychological needs.

On average, higher needs were observed in the psychological domain in this BC patients' sample, at that time of their disease trajectory and treatment location. This contrasts with the other studies using the SCNS-SF34 questionnaire on similar BC samples but in Asian countries where higher needs were evidenced in the health system and information domain [14, 16, 40, 41]. BC patients' reports of such unmet needs highlight requirement for additional active listening (e.g. to understand barriers to service access), patient education about the disease and treatment process, or referral to social services (e.g. child care assistance) or psychological counselling [42, 43] in order to help them learn efficient strategies for uncertainty or anxiety management [44].

Only satisfaction with doctors' information provision weighted on the health system and information need scale; hence, BC patients may look essentially to doctors for information provision. BC patients who had previous medical experience expressed lower needs for information and health system for similar levels of satisfaction with care compared with those with no such experience. Perhaps those BC patients with medical antecedents, more acquainted to the health-care system than novice patients, expected less response to their information needs.

At similar levels of satisfaction with care, BC patients with high psychological distress expressed higher needs for information underlining the importance of fulfilling BC women health information needs for their psychological well-being. This observation also suggests that discrepancies between specific BC patients' reported needs related to their satisfaction with care may reflect deficiencies in the care provided, which may be addressed for enhanced care targeting.

Different other factors should be explored to explain why BC patients do or do not express needs despite similar levels of difficulties. These include patient-related factors, social support [45], psychological (e.g. personality [46]), or among clinicians-related factors, gender, personality, length of relationship with patient [47], and attitude to patient's health status [48]. Among hospital-related factors, research is under-developed with regard to the role of care structure (e.g.: volume, staff-to-patient ratio, equipment, teaching/research activity, communication training available, multidisciplinary team …) or process (e.g.: guidelines, clinical case management (RCP), referral/coordination …) on response to needs in oncology [39, 49].

This study presents several limitations considering its cross-sectional design and specific ecological context. Supportive care need scales were tested as dependent variables, whereas these could have explained quality of life or satisfaction with care. Although recruited in two French-speaking nations of different health-care systems and city size, this sample may only reflect upon the BC population of these two institutions; supportive care needs have been shown to differ across cultures [15]. The consecutive recruitment approach reflects the clinical practice of the hospital services in which the study took place and the resulting sample does not allow generalization across disease stages. Moreover, respondents were younger and confronted with less advanced disease compared with non-respondents.

However, supportive care needs in relation to HRQOL and satisfaction assessments provided complementary information, which enabled to identify subgroups of BC patients who required better care in hospital services for BC treatment. Although experiencing similar degrees of symptoms, functional difficulties, or (dis)satisfaction with care aspects, particular BC patients expressed higher needs pointing to targets for care improvement. Across hospital services, BC patients' needs were mostly prevalent in the psychological domain; however, BC patients with children, with a lower level of education, or with psychological distress would require additional attention to ensure that any BC patients benefit from optimal care and treatment.

acknowledgements

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Melanoma patients in a phase I clinic: molecular aberrations, targeted therapy and outcomes

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Background: The purpose of the study was to assess the outcome of patients with advanced melanoma treated with matched molecularly targeted therapy.

Patients and methods: We reviewed 160 consecutive patients with metastatic melanoma treated in the phase I program ($N = 35$ protocols). Treatment was considered to be 'matched' ($N = 84$) if at least one drug in the regimen was known to inhibit the functional activity of at least one of the patient's mutations.

Results: Of 160 patients, 134 (83.7%) had adequate tissue for molecular analysis; 69% (110 of 160) had ≥1 mutation: 61.2% (82 of 134), *BRAF*; 20.7% (23 of 111), *NRAS*; 2.6% (2 of 77), *KIT*; 2.3% (1 of 44), *KRAS*; 20% (1 of 5), *GNAQ*; 11.1% (1 of 9), *P53* and 2.6% (1 of 39), coexisting mutations in *BRAF* and *PIK3CA*. Eighty-four patients (52.4%) were treated with matched-targeted agents, most of whom had *BRAF* mutations ($N = 74$). Twenty-six percent of patients (41 of 160) achieved a complete or partial remission (CR/PR) [40% (34 of 84)) on a matched phase I protocol versus 9.2% (7 of 76) for those on a non-matched study ($P \leq 0.0001$)]. The median progression-free survival (PFS) (95% CI) was longer for patients treated on a matched phase I trial than on their prior first standard treatment [5.27 (4.10, 6.44) versus 3.10 (1.92, 4.28) months, $P = 0.023$], but not on non-matched phase I treatment. Multivariable analysis showed that matched therapy was an independent predictor of higher CR/PR rates, prolonged PFS and survival.

Conclusions: For melanoma patients, especially those with *BRAF* mutations, administering molecularly matched agents can be associated with better outcomes, including longer PFS compared with their first-line systemic therapy.

Key words: melanoma, targeted therapy, metastatic melanoma, matched therapy, phase I

introduction

Patients with advanced melanoma are treated with palliative surgery, immunotherapy and/or chemotherapy and sometimes

radiation therapy [1–4]. Metastatic melanoma is rarely curable with standard therapeutic modalities. Current chemotherapy and cytokine-based immunotherapy [1–4] approaches benefit only a small percentage of patients with advanced disease. High-dose interleukin-2 (IL-2) [5, 6] has been reported to produce durable responses in only a small number of patients (<10%). Single-agent dacarbazine [7] has historically been the chemotherapy of choice for patients with advanced melanoma, with a response rate of 7%–15% and no overall survival (OS) benefit [7]. Other standard therapies according to National

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