

# The use of psychological supportive care services and psychotropic drugs in patients with early-stage breast cancer: a comparison between two institutions on two continents

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**Abstract** The aim of this study was to evaluate the mental health consumption among patients with early-stage breast cancer in two radiation oncology departments in two countries (USA and Italy). Data were extracted from the medical records of consecutive patients treated between 2014 and 2015 in two centers. Extracted data included patient's demographics, treatment, referral to psychological supportive care programs, and prescribed psychotropic drugs. Data from the two centers were compared using Student's *t*, Wilcoxon, Fisher's exact, and Jonckheere–Terpstra tests. Adjusted relative risks (RR) were estimated using Poisson regression. A total of 231 (Italy = 110, USA = 121) patients were included, with a mean age of 60 years. The crude rate of psychological supportive care visits was similar in the US versus the Italian cohort (28.9 vs. 21.8%,  $p = 0.23$ ). The crude rate of prescribed psychotropic drug was higher in the US cohort versus Italian cohort (43.8 vs. 18.2%,  $p < 0.0001$ ). These differences remained significant after adjusting for breast cancer subtype, stage, and treatment (RR 1.8, 95 CI 1.17–2.76). Between 20 and 30% of patients receive psychological supportive care during treatment for breast cancer. The use

of psychotropic medication was higher in the US cohort than the cohort from Italy. The reasons for these differences might be related to social and cultural differences and the method of prescribing medication.

**Keywords** Breast cancer · Distress · Survivorship · Mental health · Psychotropic drugs

## Introduction

Breast cancer is estimated to affect  $\approx 1.2$  million people worldwide [1]. Coping with cancer can be psychologically distressing, e.g., due to the diagnosis, treatment-related side effects (e.g., fatigue, lymphedema, cognitive impairment), fear of outcomes (e.g., disability, body image, fear of recurrence, marital adjustment), and social and financial difficulties [2–9]. Thus, the need for supportive care, during treatment and survivorship, appears self-evident [2, 8, 9]. However, the rate of use of supportive care services is unclear.

We herein assess the rates of mental health consumption among patients with potentially curable breast cancer in two radiation oncology departments on different continents.

## Materials and methods

### Background description of the centers

Both centers participating in this review treat a high volume of patients with breast cancer and have psychological supportive care programs for their patients. At the University of North Carolina (UNC), Chapel Hill, USA,

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the psychological supportive care services are part of the Lineberger Comprehensive Cancer Support Program (CCSP). The CCSP team is composed of psychiatrists, psychologists, clinical nurse specialists, physician assistants, social workers, counselors, volunteers, and supporting staff that work with the patient and her (or his) caregiver during cancer treatment, recovery, and survivorship. The CCSP services include mental health consultation, psychotherapy, nutritional and exercise classes, integrative medicine, and lymphedema supportive care [10]; these services are available for all cancer patients treated at UNC. Patients who are identified by the treating medical team to need support are referred for consultation. Consultation does require that the patient be evaluated by a physician specializing in mental health care unless the staff makes a referral dedicated for that reason. Medications can be prescribed by various providers (e.g., medical oncologists, radiation oncologists, surgical oncologists, nurse practitioners, and primary care physicians).

At the Florence University Hospital (FUH), the psychological supportive care services are composed of medical doctors (psychiatrists, clinical oncologists, dermatologists), professional nurses, nutritionists, physiotherapists, and support staff. Similar to UNC, patients who are identified by the medical team to need support are referred for consultation, mainly at the time of cancer diagnosis, during the triage at the local Oncological Centre for Departmental Reference (CORD). The psychological supportive care team makes a therapy plan for the patients according to their needs.

**Data extraction and analysis:** The study was approved by the institutional ethics review boards at both centers. Patient's consent was not required as this is a retrospective study involving only existing data. Data were extracted from medical records of consecutive patients with early-stage breast cancer [stages I–III] treated with curative intent, between November 2014 and December 2015, at the FUH (Italian cohort) and at the radiation oncology department, at UNC, Chapel Hill (US cohort). The study also included patients with ductal carcinoma in situ (DCIS) who were treated with postoperative radiation therapy. Data extracted included patient's demographics, cancer stage, breast cancer subtype, treatment received, referral to a supportive care program (e.g., patients whose medical record indicated that they were referred for psychological consultation but refused or patients that had a documented visit with psychiatrist), and prescribed of psychotropic drugs (mood/anxiolytic and/or sleep/sedative medications) during radiation treatment. Patients with advanced breast cancer (e.g., inoperable/metastatic or recurrent/synchronous cancer) or known psychiatric disorders or a record of psychotropic drug use prior to diagnosis of breast cancer were excluded. Melatonin for sleep disturbances is a

nonprescription medication in the USA and was not recorded as part of the sleep-aid medication. Venlafaxine prescribed for hot flashes was also excluded.

The Student's *t* tests and Chi-squared tests were used to compare the characteristics between the two cohorts. Relative risks were estimated using log-binomial regression and were presented with 95% confidence intervals. Multivariable relative risk models were fitted and controlled for variables significantly different between cohorts. All analyses were conducted using SAS statistical software v9.4 (Cary, NC).

## Results

A total of 231 patients (Italy = 110, USA = 121) were included; patient characteristics are summarized in Table 1. Differences between the two cohorts included higher T stage, more mastectomies, more preoperative systemic therapy, more nodal irradiation, and more frequently use of a radiation therapy boost in the US cohort. The crude rates of supportive care visits were similar in the US versus Italian cohorts (28.9 vs. 21.8%,  $p = 0.23$ ). The crude rates of psychotropic drug use were higher in the US versus Italian cohorts (43.8 vs. 18.2%,  $p < 0.0001$ ) (Fig. 1).

When stratified by cohort, we observed a significant association of age with both referrals to psychological supportive care services and psychotropic medications in the US cohort, but not in the Italy cohort. In the US cohort, the mean age in the patients receiving mental health referrals was lower than in the patients not receiving referrals (age 55 vs. 60 years, respectively;  $p = 0.076$ ), and the mean age of patients who were prescribed (vs. not prescribed) psychotropic medications was 53 versus 68 years, respectively ( $p = 0.0002$ ). Comparable age-related differences were not seen in the Italian cohort.

The types of psychotropic medication prescribed include benzodiazepines, antidepressants (selective serotonin and norepinephrine reuptake inhibitors), and sedatives (gamma-aminobutyric acid agonist). Table 2 summarizes patient-related, tumor-related, and treatment-related factors associated with the rate of supportive care referrals and medication use in each cohort. In the US cohort, patients with more advanced disease (positive lymph nodes and who were treated with preoperative systemic therapy), or who underwent mastectomy were more likely to be referred for use psychological supportive care services and/or psychotropic medication (vs those with less advanced disease or undergoing breast conservation). Table 3 shows adjusted relative risk models for supportive care referrals and medication use combining both cohorts. After adjusting for age, breast cancer subtype, T stage, surgery,

**Table 1** Patients' and tumor characteristics

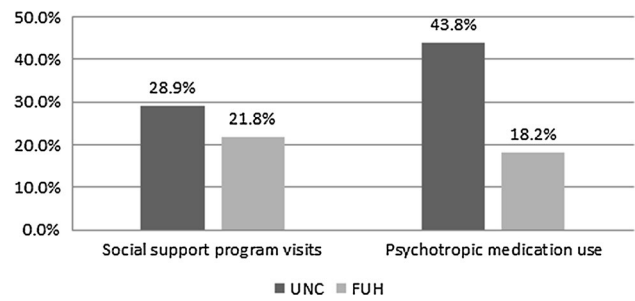
Characteristics	USA (N = 121)	Italy (N = 110)	P value
Mean age	58.88 (SD 10.7)	60.6 (SD 11.1)	0.23
<60 years	58	55	0.75
≥60 years	63	55	
Histology type			
IDC/ILC	100	96	0.33
DCIS/other	21	14	
Receptors			
HER2-/HR+	89	80	0.37
HER2 +/HR-	7	4	
HER2 +/HR +	12	18	
Triple negative	13	8	
T stage			
T0	21	10	<b>0.01</b>
T1-2	87	96	
T3-4	13	4	
N stage			
N0	80	67	0.78
N1	30	31	
N2	5	7	
N3	6	5	
Postoperative systemic therapy			
Endocrine therapy	62	62	0.13
Chemotherapy	47	30	
Missing	12	18	
Surgery			
Mastectomy	21	5	<b>0.002</b>
Lumpectomy	99	105	
Missing	1	0	
Preoperative chemotherapy			
No	98	100	<b>0.03</b>
Yes	23	10	
Regional nodal irradiation			
No	78	103	<b>&lt;0.0001</b>
Yes	43	7	
Radiation therapy boost			
No	8	17	<b>0.03</b>
Yes	113	93	

Bold values indicate statistical significance (*p* < 0.05)

IDC invasive ductal carcinoma, ILC invasive lobular carcinoma, DCIS ductal carcinoma in situ

preoperative chemotherapy, regional nodal irradiation, and the use of a radiation boost, the US patients were more likely to be prescribed psychotropic drugs compared to the Italian cohort (RR = 1.8, 95% CI 1.17–2.76). The differences in referrals to psychological supportive care services were not statistically different after adjusting for other covariates.

**Social support program visits and use of psychotropic drugs by site**



**Fig. 1** Psychological supportive care services visits and prescribed psychotropic drugs by site

**Discussion**

Our study provides a “snap-shot” of mental health consumption (psychological supportive care services and/or psychotropic drugs) of patients with non-metastatic, early-stage breast cancer treated in two centers on two continents. The study shows that up to third of the breast cancer patients who are treated in the adjuvant setting receive supportive services. This is similar to what reported by a study that evaluated distress and psychiatric disorders by performing psychiatric screening among breast cancer patients [11]. A recent study by the Turkish Oncology Group reported higher rates of psychosocial disorders and estimated that the rate of breast cancer survivors who suffer from post-mastectomy pain disorder is approximately ~45%, contributing to a high rate of post-traumatic stress disorder [7]. Another study reported that psychological symptoms (e.g., anxiety, depression, stress disorder) are encountered in up to 75% of the cancer patients [12]. These data emphasize the need to have specialized comprehensive services available for patients as patients’ need of support that are often not addressed by the cancer treating medical team [3, 11, 13, 14]. A cancer diagnosis is often overwhelming to a patient even if it is diagnosed at an early-stage of disease. The period following diagnosis of breast cancer is usually occupied by a complex decision-making for primary therapy (e.g., extent of surgery, cancer subtype, systemic therapy, radiation) and, for most women, systemic therapy that takes place over the next 4–6 months, or even longer for HER2 positive patients or for those who receive endocrine therapy. During that time, there is an increased sense of uncertainty, and existential concerns, leading to the sense of vulnerability, even in the setting of curative disease. The fear of cancer recurrence was described in a number of studies to be a major factor that contributes to patient distress and need for psychological support even in patients with early-stage disease [8]; this was estimated to affect up to 70% of survivors and may

**Table 2** Unadjusted relative risk for supportive care referrals and medication use

Characteristics	USA		Italy	
	Supportive care visits	Psychotropic medication	Supportive care visits	Psychotropic medication
Age				
<60 years	1.00	1.00	1.00	1.00
≥60 years	0.61 (0.35, 1.09)	<b>0.60* (0.40, 0.92)</b> <i>P</i> = 0.018	1.40 (0.68, 2.88)	1.86 (0.80, 4.30)
Histology type				
IDC/ILC	1.00	1.00	1.00	1.00
DCIS/other	0.29 (0.08, 1.11)	<b>0.39* (0.16, 0.96)</b> <i>P</i> = 0.04	0.30 (0.04, 2.04)	0.36 (0.05, 2.49)
Receptors				
HER2-/HR+	1.00	1.00	1.00	1.00
HER2 +/HR-	1.11 (0.33, 3.76)	1.41 (0.71, 2.81)	1.33 (0.23, 7.73)	1.82 (0.31, 10.82)
HER2 +/HR +	1.29 (0.54, 3.09)	1.44 (0.84, 2.48)	1.78 (0.80, 3.94)	<b>2.42** (1.03, 5.69)</b> <i>P</i> = 0.04
Triple negative	1.79 (0.90, 3.54)	1.14 (0.60, 2.16)	1.33 (0.37, 4.81)	1.82 (0.49, 6.80)
T stage				
T0	0.33 (0.09, 1.29)	<b>0.39* (0.16, 0.98)</b> <i>P</i> = 0.04	0.44 (0.07, 2.90)	0.53 (0.08, 3.59)
T1-2	1.00	1.00	1.00	1.00
T3-4	<b>2.14** (1.24, 3.68)</b> <i>P</i> < 0.001	1.12 (0.64, 1.93)	1.09 (0.19, 6.19)	1.33 (0.23, 7.66)
N stage				
N0	1.00	1.00	1.00	1.00
N1	1.33 (0.67, 2.64)	<b>1.95** (1.28, 2.96)</b>	1.01 (0.46, 2.22)	0.62 (0.22, 1.72)
N2	<b>2.67** (1.17, 6.07)</b> <i>p</i> = 0.019	1.85 (0.84, 4.04)	1.28 (0.36, 4.47)	1.37 (0.39, 4.82)
N3	<b>3.70** (2.15, 6.37)</b> <i>P</i> = 0.0001	<b>2.56** (1.59, 4.13)</b> <i>P</i> = 0.0001	N/A	N/A
Postoperative systemic therapy				
HT	1.00	1.00	1.00	1.00
Chemotherapy	1.51 (0.82, 2.77)	<b>2.10** (1.30, 3.37)</b> <i>P</i> = 0.0022	0.96 (0.44, 2.11)	1.03 (0.43, 2.49)
Surgery				
Mastectomy	<b>2.25** (1.31, 3.88)</b> <i>P</i> = 0.0033	0.96 (0.56, 1.66)	1.91 (0.61, 5.95)	2.33 (0.74, 7.39)
Lumpectomy	1.00	1.00	1.00	1.00
Preoperative chemotherapy				
No	1.00	1.00	1.00	1.00
Yes	<b>1.95** (1.13, 3.39)</b> <i>P</i> = 0.172	1.25 (0.79, 1.97)	0.91 (0.25, 3.31)	1.11 (0.30, 4.11)
Regional nodal irradiation				
No	1.00	1.00	1.00	1.00
Yes	<b>1.92** (1.11, 3.32)</b> <i>P</i> = 0.019	<b>1.88** (1.28, 2.78)</b> <i>P</i> = 0.0014	1.34 (0.39, 4.57)	1.63 (0.47, 5.67)
Radiation therapy boost				
No	0.42 (0.07, 2.65)	0.55 (0.16, 1.87)	0.78 (0.26, 2.33)	0.97 (0.32, 2.94)
Yes	1.00	1.00	1.00	1.00

Bold values indicate statistical significance ( $p < 0.05$ )

IDC invasive ductal carcinoma; ILC invasive lobular carcinoma; DCIS ductal carcinoma insitu

Results are showing relative risk, with a 95% confident interval

\* A relative risk lower than one is an indicator for reduced risk for supportive care referrals or medication use

\*\* A relative risk greater than one is an indicator for increased risk for supportive care referrals or medication use. *P* value are only shown if found significant

persist for many years. Psychological distress focused on fear was observed more often in younger patients and women [15]. Fear of recurrence was found to be associated with refusal of the patient to discontinue follow-up in an oncology center, increased emergency care visits, unscheduled visits to primary medical care, and the use of complementary and alternative medicine [8, 15]. Providing comprehensive specialized support early in the phase of the disease may influence the patient's quality of life in the long term, by addressing the needs for social, spiritual, psychological, and physical well-being [16].

There are substantial differences between the availability of these services between various centers [13]. One study indicated that these differences were associated with center specialty (e.g., greater support in centers specialized in breast cancer), type of center (e.g., university hospital vs. other), and location (e.g., rural areas vs other, with less availability in rural areas) [13].

There is not much data comparing the differences in psychotropic medication, psychiatric diseases, or psychological supportive care programs for cancer patients between the USA and Europe. An analysis published in 2007, for the general population, indicated an increase in the use of psychotropic drug in the USA, mainly due to an increase in antidepressants use, while the rate of anxiolytic and hypnotic medications remained constant [17]. These trends of increase in psychotropic medication were also demonstrated in Europe [18]. A meta-analysis that evaluated the rates of psychiatric disorders (depression, anxiety, and adjustment disorder) among cancer patients in various settings (e.g., breast surgery, palliative, hemato-oncology) indicated that there is insufficient data to correlate these disorders according to country; however, data showed that the prevalence of depression was higher in the USA (22%) compared to the UK (17%) in the non-palliative setting [19].

These parameters are difficult to compare. Moreover, the presence of distress does not indicate there is a need for medical intervention. A study by the University of Pennsylvania reported that up to 52% of breast cancer patients received psychotropic medication during treatment, including almost half (48%) of those without a psychiatric diagnosis [11]. The rate of psychotropic medication prescriptions in the US cohort (43.2%) was similar to that reported by the University of Pennsylvania and was higher compared the Italian cohort (18.2%). In the general US population, it was reported that female gender was found to be associated with the use of psychotropic medication [17]. Another possible factor that can contribute to the higher rate of psychotropic medications is the differences in protocols of how these medications are prescribed. At UNC, the psychotropic medications were prescribed by various providers (e.g., primary physician, medical oncologists, radiation oncologists, nurse practitioners), whereas in FUH

(Italian cohort), the supportive care team makes the medical intervention therapy plan for the cancer patients. The medical staff can make minor adjustments for psychotropic medication, but mostly, it is done under the supervision/instruction of the supportive care team. Moreover, patients are often referred on demand during cancer treatments and follow-up to supportive care team for further evaluation and modification of psychotropic medications. A supervised medication administration approach prescribed by a specialized mental health team, assuming that these services are easily accessible, might provide a good means to monitor appropriate use of these medications according to the patient's mental health.

In the current study, we evaluated the correlation between disease-related factors (e.g., stage, cancer subtype) and treatment-related factors (e.g., preoperative/postoperative chemotherapy, use of radiation boost) to the rate of referrals to psychological supportive care programs and psychogenic medication. We selected disease-related factors and treatment-related factors, since they are more comparable parameters between the two cohorts (as opposed to ethnic and cultural factors), and might be easy parameters to identify patients in distress in daily practice (e.g., younger patients). Moreover, these factors dictate the type of treatment and/or duration of treatment (e.g., the use of radiation therapy boost results in a longer radiation course; as does prolonged anti-HER2 directed therapy) and are potential sources for distress for these patients. Indeed, factors such as younger age, extent of surgery (mastectomy), and postoperative chemotherapy were found to be associated with post-traumatic stress disorder in breast cancer survivors (reported in up to 35% of survivors) [7]. In addition, a study that evaluated psychological distress among curative breast cancer patients reported that at 3 months post-diagnosis, up to 39% of the patients who underwent lumpectomy were found to have evidence of emotional distress compared to 25.8% who underwent mastectomy. The authors related these differences to the findings that lumpectomy patients were younger and had more adjuvant treatments (chemotherapy, radiation therapy) [20].

The current study has several limitations. First, the retrospective nature raises all of the common shortcomings of such studies. However, this is the largest study of its nature to address this issue. We did not analyze the course of this mental health consumption over time (how long did these patients continue these medications, etc.). However, distress at time of diagnosis and initial treatment have been described in previous studies as valid time points to evaluate emotional distress in this population [20–22].

In summary, the relatively high rate of referrals to supportive care services (up to third of the patients), and in the prescription of psychotropic drugs speaks to the emotional stress that patients with breast cancer can experience.

**Table 3** Adjusted relative risk for psychological supportive care referrals and medication use

Characteristics	Supportive care visits	Psychotropic medication
Site		
USA	1.14 (0.68, 1.93)	<b>1.80** (1.17, 2.76)</b>
Italy	1.00	1.00
T stage		
T0	0.42 (0.13, 1.29)	0.59 (0.29, 1.22)
T1-2	1.00	1.00
T3-4	1.32 (0.71, 2.45)	1.17 (0.54, 2.53)
Surgery		
Mastectomy	1.90 (0.82, 4.39)	0.59 (0.31, 1.09)
Lumpectomy	1.00	1.00
Preoperative chemotherapy		
No	1.00	1.00
Yes	1.22 (0.72, 2.09)	0.82 (0.55, 1.23)
Regional nodal irradiation		
No	1.00	1.00
Yes	0.91 (0.41, 2.02)	<b>2.10** (1.41, 3.14)</b>
Radiation therapy boost		
No	0.57 (0.22, 1.44)	0.90 (0.45, 1.82)
Yes	1.00	1.00

Bold values indicate statistical significance ( $p < 0.05$ )

IDC invasive ductal carcinoma, ILC invasive lobular carcinoma, DCIS ductal carcinoma insitu

Results are showing relative risk, with a 95% confident interval, a relative risk greater than one is an indicator for increased risk for supportive care referrals or medication use

\*\* A relative risk greater than one is an indicator for increased risk for supportive care referrals or medication use. *P* value are only shown if found significant

Thus, psychological supportive care programs are likely an important part of the multidisciplinary management [2, 23–27]. Patients who are experiencing distress or need social support should be identified, and associated coping tools should be made available. Further studies are needed to understand the causes and treatment implications of the differences in medical interventions noted between these two populations, and whether it reflects a difference in practice between Europe and USA.

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#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors. The study was approved by the institutional ethic review boards at both centers.

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