

Patient-Reported Treatment Satisfaction Among Women Receiving Palbociclib Combination Therapies for HR+/HER2- Advanced or Metastatic Breast Cancer in the United States

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BACKGROUND

- Breast cancer is the most common cancer worldwide among women. A recent study estimated that approximately 3.5 million women in the United States (US) had a diagnosis of breast cancer (any stage) in 2016.¹
- In 2013, an estimated 138,622 women in the US were alive with metastatic breast cancer, 38,897 of whom (28%) were diagnosed initially with stage IV disease (“de novo” cases) and 99,725 of whom (72%) were diagnosed initially with more limited stages of disease that later progressed.²
- An estimated 50,344 new cases of metastatic breast cancer were diagnosed among women in the same year in the US (12,966 “de novo” [26%] and 37,378 that had progressed [74%]).² In 2017, it is estimated that 40,610 women died of breast cancer in the US.³
- Approximately 72% of newly diagnosed breast cancer cases of known hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) subtype were HR+ and HER2-.⁴
- Palbociclib in combination with aromatase inhibitors (AI) or fulvestrant has been approved for HR+/HER2- advanced/metastatic breast cancer (ABC/MBC).
- There is limited information on patient satisfaction with palbociclib combination therapies post approval.

OBJECTIVE

- To assess treatment satisfaction among women receiving palbociclib combination therapies for HR+/HER2- ABC or MBC in the US.

MATERIALS AND METHODS

- The study was an observational, cross-sectional, web-based survey of patients with HR+/HER2- ABC/MBC in the US.
- Patients were identified and recruited through an online panel and recruiter proprietary databases. Screening questions targeted patients with self-reported ABC or MBC.
- Patients were ≥ 18 years old and currently taking palbociclib + AI or palbociclib + fulvestrant for ≥ 2 months.
- A 38-item questionnaire was developed to describe patient demographics and treatment and medical history, and to measure satisfaction with therapy. The questionnaire included screener questions to confirm eligibility, an informed consent, and the Cancer Treatment Satisfaction Questionnaire (CTSQ).
- The study recruited 250 patients with HR+/HER2- ABC/MBC from September to November 2017.
- Descriptive statistics are reported for the overall cohort, by combination drug used (AI or fulvestrant), and by sites of metastases (visceral or nonvisceral sites).

Cancer Therapy Satisfaction Questionnaire

- Satisfaction was measured using the CTSQ, which assesses three domains (Table 1):
 - Expectations of therapy in preventing recurrence or progression or returning to normal life (ET)
 - Feelings about side effects (FSE)
 - Satisfaction with therapy (SWT)
- Each domain is scored from 0 to 100, with a higher score indicating better outcomes.
- The CTSQ was developed for use in patients with any type of cancer regardless of the stage and treatments used.⁵
- Responses and scores were analyzed descriptively through the tabular display of summary statistics (i.e., mean, standard deviation [SD], median, and range) for continuous variables and frequency counts and percentages (of the total number of nonmissing responses) for categorical variables.
- No imputation of missing data was performed.
- CTSQ scoring was conducted per the CTSQ scoring guide; 95% confidence intervals for the mean were calculated for each of CTSQ domain score.
- Pairwise comparisons of mean CTSQ domain scores between patients with visceral and nonvisceral disease were carried out using t-tests and P values and were reported without adjustment for multiple comparisons.

Domain	Description
Expectations of therapy	Return back to a normal life
	Get rid of the cancer
	Prevent cancer from coming back
	Stop the cancer from spreading
	Help you live longer
Feelings about side effects	Palbociclib limited daily activities
	Upset about the side effects
	Taking palbociclib as difficult as expected
	Were side effects as expected
	Worth taking even with the side effects
Satisfaction with therapy	Thinking about stopping palbociclib
	How worthwhile was palbociclib
	Benefits of palbociclib meet expectations
	Satisfaction with form of palbociclib
	Satisfaction with recent palbociclib
	Would you take palbociclib again

Adapted from Pfizer, 2006.* For this study, “TV/pills” was substituted with “Ibrance (palbociclib)” for specificity.

RESULTS

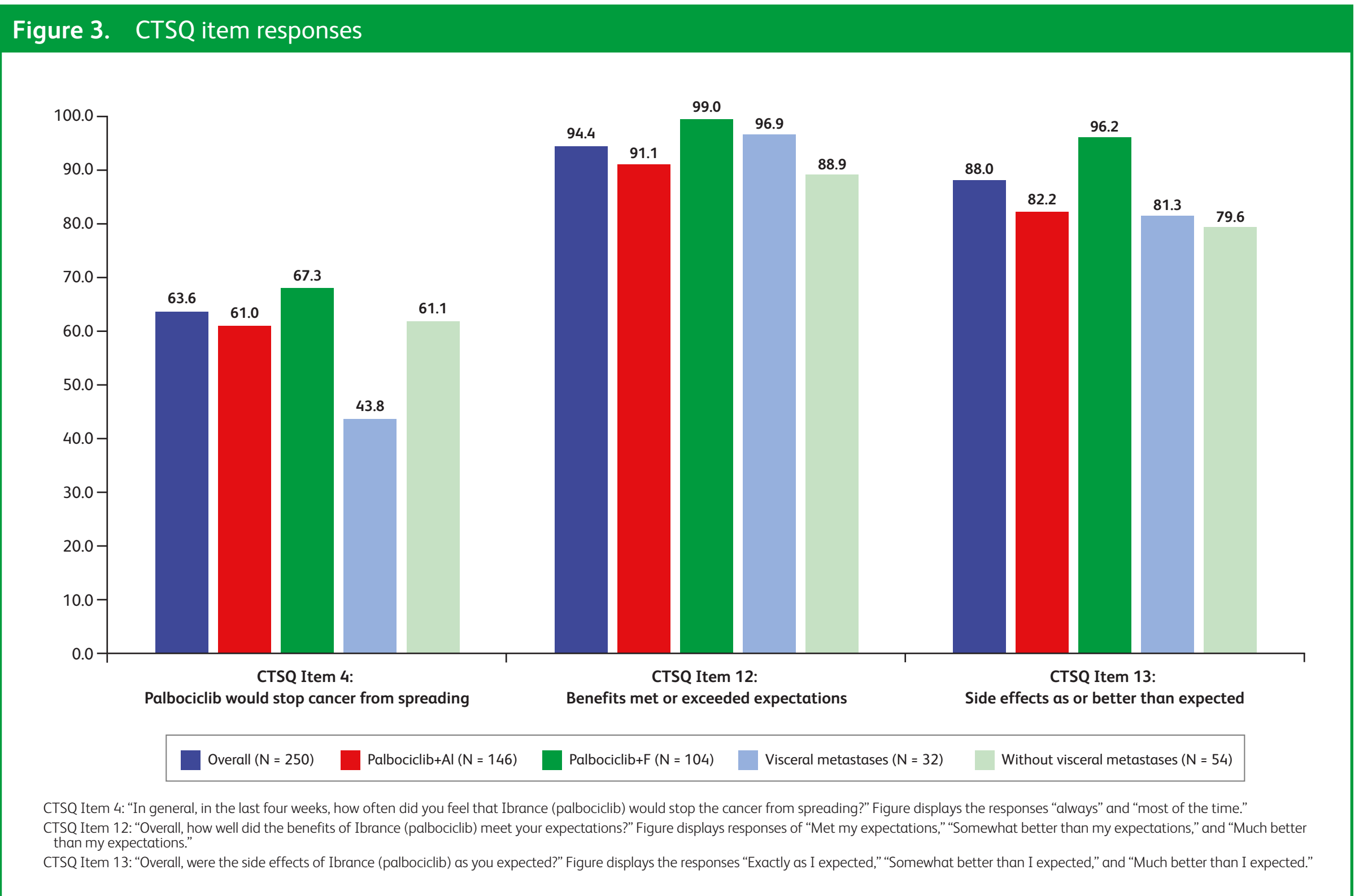
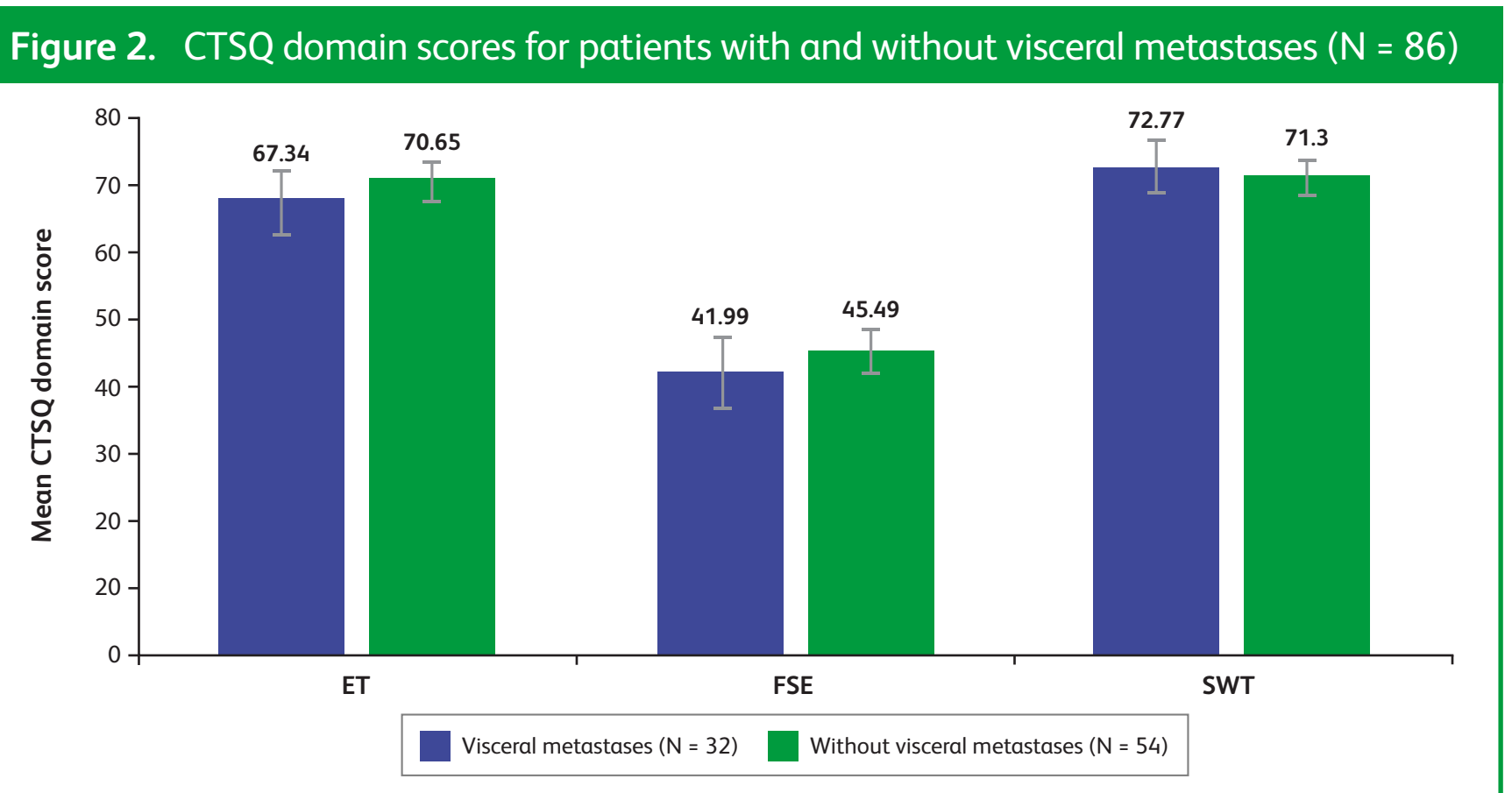
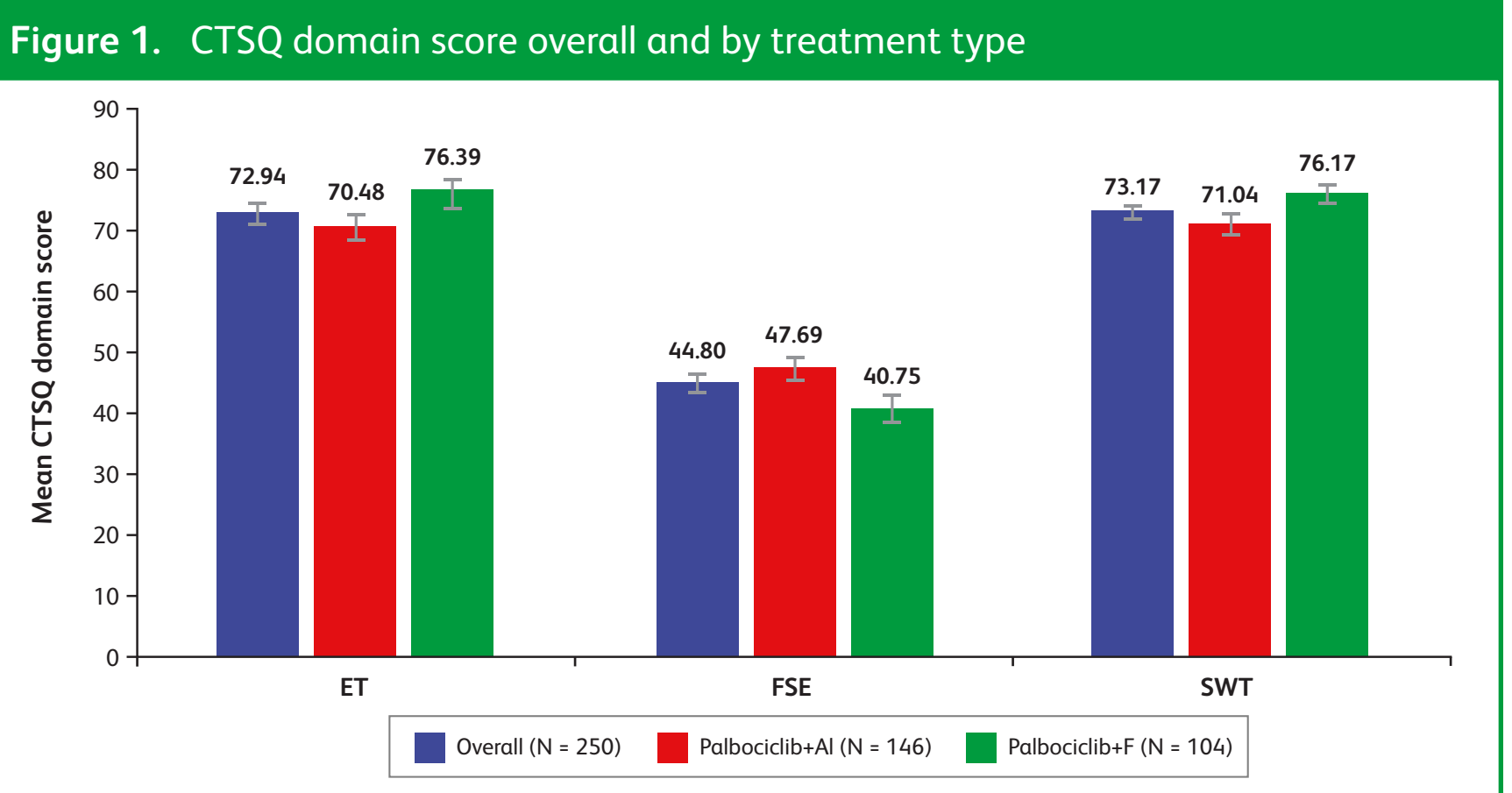
- The survey was completed by 250 patients. Patient characteristics are displayed in Table 2. The majority of patients were Caucasian (87.6%), were employed full-time (54.4%), and held an undergraduate or graduate degree (68%). Median age was 40 years, and approximately 58% (n = 146) of the study population had received palbociclib + AI.
- Overall mean (SD) time since diagnosis of ABC/MBC was 16.9 (38.82) months; 72.8% were initially diagnosed with ABC/MBC while the remaining recurred from earlier stages.
- 86 patients with MBC indicated site(s) of metastases. Of these, 37.2% had visceral metastases. Treatment and medical history of patients are displayed in Table 3.

CTSQ domain scores

- CTSQ domain scores are summarized in Figure 1. Average (SD) SWT scores were high in patients treated with palbociclib + AI (71.04 [12.18]) and in patients treated with palbociclib + fulvestrant (76.17 [9.91]).

Characteristic	Overall (N = 250)
Age (years)	
Mean (SD)	40.0 (7.98)
Median	40
18-49 (n, %)	221 (88.4%)
50-64 (n, %)	27 (10.8%)
65+ (n, %)	2 (0.8%)
Race or ethnicity* (n, %)	
White/caucasian	219 (87.6%)
African/black	29 (11.6%)
Other	6 (2.4%)
Prefer not to answer	2 (0.8%)
Employment status* (n (%))	
Employed full-time	136 (54.4%)
Employed part-time	17 (6.8%)
Homemaker	61 (24.4%)
Student	4 (1.6%)
Unemployed	13 (5.2%)
Retired	7 (2.8%)
Disabled	4 (1.6%)
Short-term inability to work due to cancer	4 (1.6%)
Long-term inability to work due to cancer	9 (3.6%)
Prefer not to answer	1 (0.4%)
Education level, n (%)	
Less than high school diploma	1 (0.4%)
High school diploma	24 (9.6%)
Some college or university	54 (21.6%)
University or undergraduate degree	118 (47.2%)
Professional, advanced, or graduate degree	52 (20.8%)
Prefer not to answer	1 (0.4%)

* Patients could select more than one response.

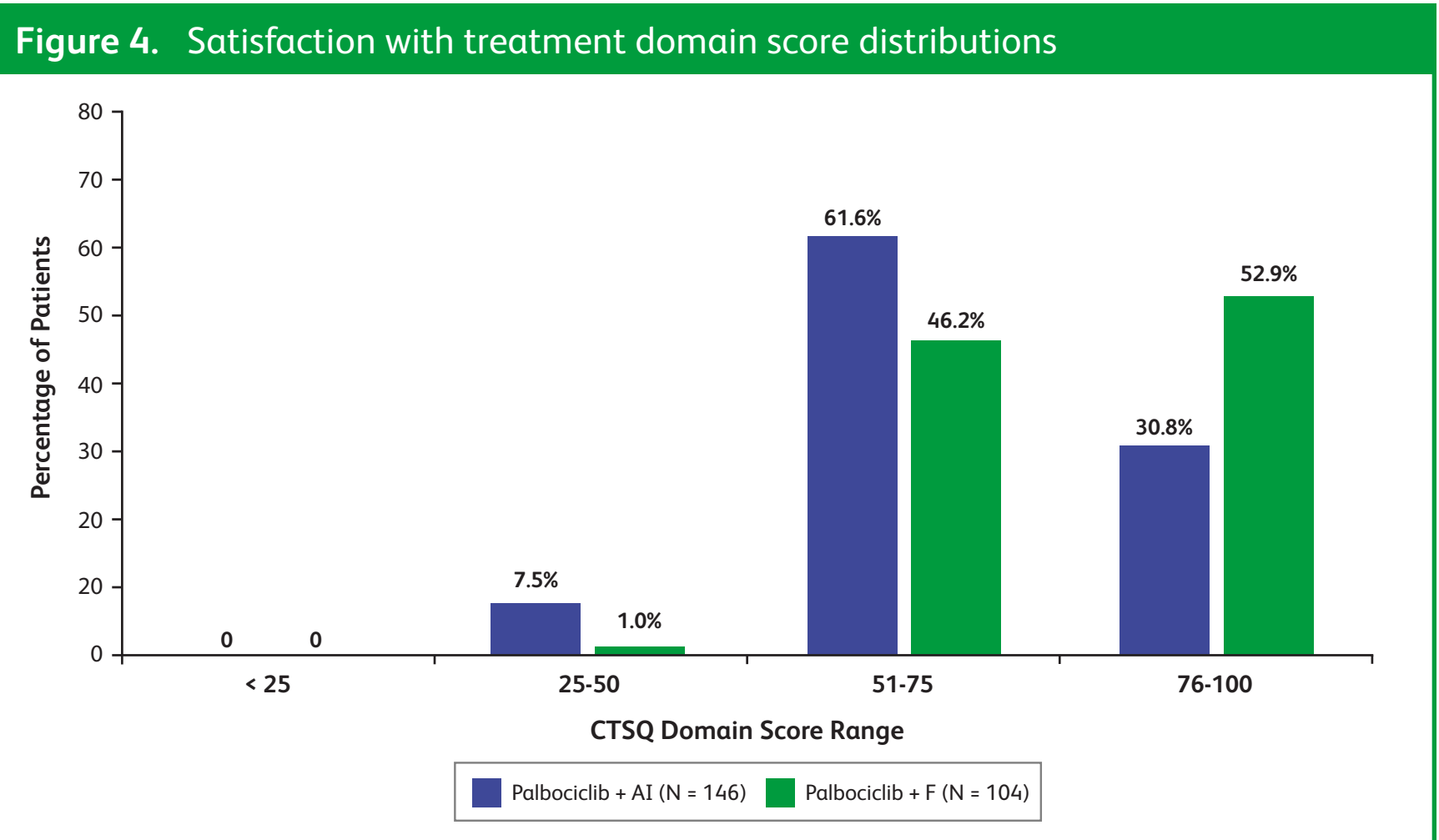


- Average (SD) expectations of therapy scores were 70.48 (16.11) with palbociclib + AI and 76.39 (15.05) with palbociclib + fulvestrant, respectively.
- Average (SD) scores for FSE were 47.69 (14.90) for palbociclib + AI and 40.75 (13.55) for palbociclib + fulvestrant.
- Mean (SD) ET, FSE, and SWT domain scores were similar between patients with visceral metastases. Results are displayed in Table 4 and Figure 2.
- Select CTSQ item results are displayed in Figure 3.
- Patients taking palbociclib + AI and palbociclib + fulvestrant reported high satisfaction with treatment scores. Over 30% of patients on palbociclib + AI and over 52% on palbociclib + fulvestrant had satisfaction scores >75 (Figure 4).
- 61% of patients taking palbociclib + AI and 67% of patients taking palbociclib + fulvestrant expected that their therapy would stop the cancer from spreading (CTSQ Item 4). Overall, 77% felt that their therapy would help them return to a normal life.
- More than 90% of patients reported that the benefits of their palbociclib combination therapy met or exceeded their expectations (CTSQ Item 12), and 79% felt that their therapy was “quite” or “very” worthwhile ($\geq 75\%$ of patients with or without visceral metastases).

	Overall (N = 250)
Current treatment, n	250
Palbociclib + AI*	146 (58.4%)
Palbociclib + fulvestrant	104 (41.6%)
Stage when breast cancer was first diagnosed, n	250
Early-stage breast cancer (stage I, IIA, IIB, and IIIA), n (%)	68 (27.2%)
Advanced breast cancer (stage IIIB and IIIC), n (%)	96 (38.4%)
Metastatic breast cancer (stage IV), n (%)	86 (34.4%)
Mean time since diagnosis of ABC or MBC (months)	16.9 (38.82)
Visceral status, n	86
Visceral metastases, n (%)	32 (37.2%)
No visceral metastases, n (%)	54 (62.8%)

*AIs included anastrozole, exemestane, and letrozole.
 Visceral status was derived and included metastases of the brain, liver, lungs/pleura, and pancreas. No visceral metastases included bone, lymph nodes, and skin/soft tissue.

- More than 80% of patients in each treatment group indicated that side effects were as or better than expected (CTSQ Item 13). Patients with and without visceral metastases reported similar responses regarding side effects (81% and 80%, respectively).
- Overall, 89% of patients were satisfied with their most recent palbociclib therapy (CTSQ Item 15). Patients taking palbociclib + fulvestrant reported a higher level of satisfaction with their most recent therapy (97% reported “satisfied” or “very satisfied”), while 84% of patients taking palbociclib + AI reported satisfaction with their most recent therapy. Satisfaction was similar for patients with (84%) and without (89%) visceral metastases.
- Overall, 95% indicated that, taking everything into consideration and if given the choice again, they would take palbociclib again.
- Overall, only 12.8% of patients felt that taking palbociclib was much more difficult than expected (CTSQ Item 11).



CTSQ domain	All patients with metastases (N = 86)	Visceral metastases (N = 32)	Without visceral metastases (N = 54)
Expectations of therapy			
Mean (SD)	69.42 (13.92)	67.34 (15.96)	70.65 (12.55)
Median	70	62.5	70
Min, Max	35, 100	40, 100	35, 100
Feelings about side effects			
Mean (SD)	44.19 (15.42)	41.99 (17.26)	45.49 (14.23)
Median	43.8	40.6	50
Min, Max	13, 81	13, 81	13, 81
Satisfaction with therapy			
Mean (SD)	71.84 (12.13)	72.77 (12.69)	71.30 (11.87)
Median	71.4	71.4	71.4
Min, Max	36, 100	50, 100	36, 93

LIMITATIONS

- This was a web-based survey of patients who self-selected to participate in research studies. Invitations were distributed to research panel members who had a self-reported physician diagnosis of breast cancer. Therefore, the panel population and those who agreed to participate in this study may not be representative of the overall ABC/MBC population.
- Patients with advanced disease may not be able to complete or have interest in online surveys.
- Disease characteristics and treatments received are documented based on participant self-report; no corroboration with medical records or physicians was conducted.

CONCLUSION

- The majority of patients indicated that the benefits of palbociclib exceeded their expectations.
- Patients reported having high expectations of therapy with palbociclib + AI and palbociclib + fulvestrant.
- Patients reported high satisfaction scores with palbociclib combined with AI and palbociclib combined with fulvestrant.
- Satisfaction levels were similar for palbociclib combination-treated patients with and without visceral metastases.
- The majority of patients taking palbociclib + AI and palbociclib + fulvestrant reported that side effects were as expected or better than expected.

REFERENCES

- Miller KD, Siegel RL, Lin CC, Mariotto AB, Kramer JL, Rowland JH, et al. Cancer treatment and survivorship statistics, 2016. *CA Cancer J Clin.* 2016;66:271-89.
- Mariotto AB, Etzioni R, Hurlbert M, Penberthy L, Mayer M. Estimation of the Number of Women Living with Metastatic Breast Cancer in the United States. *Cancer Epidemiol Biomarkers.* 2017;809-15.
- National Cancer Institute: Surveillance, Epidemiology, and End Results Program. Cancer Stat Facts: Female Breast Cancer. Available at <https://seer.cancer.gov/statfacts/html/breast.html>. Accessed February 9, 2018.
- Howlander N, Altekruze SF, Li CI, Chen VW, Clarke CA, Ries LA, Cronin KA. US incidence of breast cancer subtypes defined by joint hormone receptor and HER2 status. *J Natl Cancer Inst.* 2014 Apr 28;106(5).
- Abetz MA, Coombs JH, Keininger DL, Earle CC, Wade C, Bury-Maynard D, et al. Development of the Cancer Therapy Satisfaction Questionnaire: item generation and content validity testing. *Value Health.* 2005;5:41-53.
- Pfizer Patient Reported Outcomes. Administration and scoring guide for the Cancer Therapy Satisfaction Questionnaire (CTSQ). 2006. Available at https://www.pfizerpatientreportedoutcomes.com/system/files/pdf/scoring_ctsq.pdf. Accessed December 6, 2017.

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