#2272: Integrating Mental Health in Oncology: A Review of Psychiatric Symptom Monitoring in Recent Breast Cancer Trials

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Abstract

Background: Breast cancer (BC) patients face a lifelong disease burden that includes significant psychological stress. While clinical trials often focus on treatment efficacy and physical toxicities, psychiatric side effects remain underrecognized despite their potential to impact quality of life, adherence, and outcomes. This study evaluated the extent to which psychiatric symptoms were monitored and reported in Phase III clinical trials of FDA-approved BC treatments over the past decade.

Methods: We reviewed the FDA archives to identify BC treatments approved over the past decade and found 21 such treatments. We conducted a search on clinicaltrials.gov to identify Phase III trials evaluating these FDA-approved interventions initiated after January 1, 2015, with posted results. The search yielded 38 clinical trials, comprising a total of 26,298 participants. We then examined each trial cohort for the presence of reported psychiatric symptoms. Trial protocols were reviewed in detail to identify the specific assessment tools and criteria for monitoring psychiatric symptoms, including documentation during treatment and post-treatment follow-up. All symptoms were recorded as adverse events for each trial per the NCI CTCAE guidelines. Most trials reported symptoms only during the treatment period. Descriptive statistics were used for data analysis.

Results: Among the 38 phase III trials, 37 (97%) reported at least one psychiatric symptom. The most frequently reported symptom was insomnia, affecting 2563 participants (9.7%), while nervousness was the least reported, documented in only 1 participant. Other reported symptoms included anxiety, stress, depression, suicide attempts or completions, and confusional states. The most used assessment tool was EORTC-QLQ C30, followed by EQ-5D-5L, NCI-PRO-CTCAE, and FACT-B. Additional psychiatric symptoms, such as disorientation, apathy, panic attacks, stress, mania, psychiatric decompensation, mental disorders and sleep disorders, were identified but inconsistently assessed across trials. Most trials recorded psychiatric symptoms only during the treatment period, with limited documentation in long-term follow-up.

Conclusion: While most trials reported at least one psychiatric symptom, monitoring was largely limited to short-term effects, highlighting the narrow scope of assessment. Inconsistent use of tools and limited follow-up suggest psychiatric symptoms remain underrecognized. This study is limited by reliance on publicly available data and potential reporting bias. A more holistic and longitudinal approach to psychiatric symptom monitoring can significantly improve patient safety to ensure treatment adherence without compromising their well-being.

Introduction

- Breast cancer (BC) patients face a lifelong disease burden that includes significant psychological stress.
- While clinical trials often focus on treatment efficacy and physical toxicities, psychiatric side effects remain underrecognized despite their potential to impact quality of life, adherence, and outcomes.
- This study evaluated the extent to which psychiatric symptoms were monitored and reported in Phase III clinical trials of FDA-approved BC treatments over the past decade.

Methods and Materials

- **Data Source:**
  - -Reviewed **FDA archives** to identify **BC treatments approved** within the **past decade.**
  - A total of **21 FDA-approved treatments** were identified.
- **Clinical Trial Identification:**
  - Conducted a **ClinicalTrials.gov** search for **Phase III** trials evaluating these treatments.
  - Included trials **initiated after January 1, 2015**, with **posted results.**
  - **38 eligible trials** identified, enrolling **26,298 participants**.
- **Psychiatric Symptom Assessment:**
  - Each trial cohort was reviewed for **reported psychiatric symptoms.**
  - **Trial protocols** examined to identify:
    Assessment tools and **monitoring criteria** used.
    Documentation **during treatment and post-treatment** follow-up periods.
- **Adverse Event Reporting:**
  - All psychiatric symptoms classified as **adverse events (AEs)** per **NCI CTCAE guidelines**.
  - Most trials reported symptoms **only during active treatment,** post-treatment data were limited.
- **Statistical Analysis:**
  - **Descriptive statistics** for data summarization and analysis.

Table 1. Psychiatric symptoms monitoring in FDA-approved breast cancer trials- 2015-2025

Symptoms	Trials (n= 37)	Participants (n=26,298)
Insomnia	36	2563 (9.75%)
Anxiety	20	524 (1.99%)
Depression	21	484 (1.84%)
Confusional state	12	23 (0.09%)
Suicide Attempts/Completions	8	12 (0.05%)
Delirium	3	6 (0.02%)
Mental status change	5	5 (0.02%)
Bipolar disorder	2	3 (0.01%)
Agitation	2	2 (0.01%)
Nervousness	1	1 (0.00%)

Future Directions

- Implement a **holistic and longitudinal approach** to psychiatric symptom monitoring.
- Improve **consistency of reporting** and **standardize assessment tools.**
- Enhance **patient safety** and **treatment adherence** while promoting overall well-being.

Results

- **Trial Overview:**
  - **38 Phase III** trials were analyzed.
  - **37 trials (97%)** reported at least **one psychiatric symptom.**
- **Most Common Symptoms:**
  - **Insomnia** was the most frequently reported, affecting **2,563 participants (9.7%).**
  - **Nervousness** was the least reported, documented in **1 participant.**
  - Other symptoms included **anxiety, stress, depression, suicide attempts or completions, and confusional states.**
- **Assessment Tools:**
  - The most commonly used tool was **EORTC-QLQ C30.**
  - Other instruments included **EQ-5D-5L, NCI-PRO-CTCAE,** and **FACT-B.**
- **Additional Reported Symptoms:**
  - **Disorientation, apathy, panic attacks, stress, mania, psychiatric decompensation, mental disorders,** and **sleep disorders** were also identified.
  - These were **inconsistently assessed** across trials.
- **Timing of Documentation:**
  - Most trials recorded psychiatric symptoms **only during treatment.**
  - **Long-term follow-up** data were **limited.**

Conclusions

- While most trials reported at least one psychiatric symptom, monitoring was **largely limited to short-term effects**, highlighting the **narrow scope of assessment.**
- **Inconsistent use of tools** and **limited follow-up** suggest **psychiatric symptoms remain underrecognized** in BC trials.
- **Study limitations:**
  - Reliance on **publicly available data**.
  - Potential **reporting bias** across trial registries.

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