

# Patient Reported Outcomes With Chemotherapy of Breast Cancer: An Analysis of Breast Cancer Registry Publications Between 2012-2022

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## Background

- Cancer registries represent real-world data of patients with cancer
- There are three main types of cancer registries: Population-based registries (PBCR), hospital-based cancer registries (HBCR) – single centre, and HBCR – collective<sup>1</sup>
- Information retrieved from cancer registries can reveal the impact of the treatment of cancer in the real-world
- Chemotherapy for breast cancer can significantly impact the quality of life (QoL) and other patient-reported outcomes (PROs)<sup>2</sup>
- Many randomized controlled trials (RCTs) on breast cancer chemotherapy collect PROs as a part of outcome measures
- We were interested to examine PROs among breast cancer patients receiving chemotherapy in the real-world setting

## Objective

- To descriptively evaluate the nature and extent of reporting of patient-reported outcomes (PROs) among patients with breast cancer undergoing chemotherapy (with or without other types of therapies) in published registry audit articles

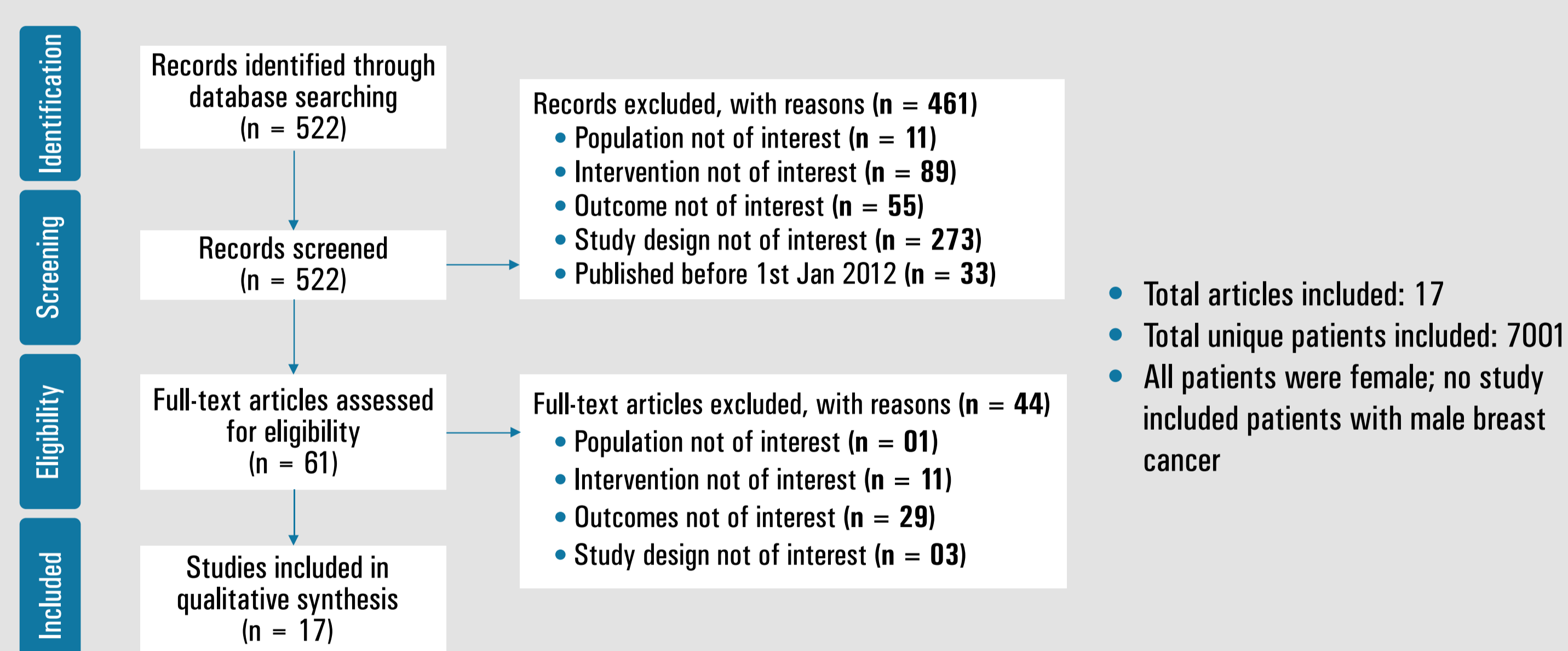
## Methodology

### Eligibility Criteria

Facet	Inclusion	Exclusion/ Not of interest (NOI)
Population	<ul style="list-style-type: none"> <li>• Humans suffering from any stage and form of breast cancer</li> <li>• No restrictions on age, gender, race, stage, immuno histological type</li> </ul>	<ul style="list-style-type: none"> <li>• Humans without breast cancer</li> <li>• No human subjects</li> </ul>
Intervention	<ul style="list-style-type: none"> <li>• Chemotherapy, either alone or in combination with other modalities of breast cancer treatment (immunotherapy, endocrine therapy, surgery, radiotherapy etc)</li> </ul>	<ul style="list-style-type: none"> <li>• Chemotherapy not used in breast cancer treatment</li> </ul>
Comparator	<ul style="list-style-type: none"> <li>• Any comparator</li> </ul>	<ul style="list-style-type: none"> <li>• No restriction</li> </ul>
Outcome	<ul style="list-style-type: none"> <li>• PROs: quality of life, patient satisfaction, all other PROs</li> </ul>	<ul style="list-style-type: none"> <li>• All other outcomes</li> </ul>
Study design	<ul style="list-style-type: none"> <li>• Analysis of some type of registries (disease, cancer, population, hospital, etc)</li> </ul>	<ul style="list-style-type: none"> <li>• All other types of papers</li> </ul>
Databases	<ul style="list-style-type: none"> <li>• PubMed</li> </ul>	
Date range	<ul style="list-style-type: none"> <li>• Published in the last decade (from 01 Jan 2012 till date)</li> </ul>	<ul style="list-style-type: none"> <li>• Older papers</li> </ul>

Note: Restrictions were not imposed on the search strategy; ineligible articles were manually screened out

## Results



## Publication Information

<b>Study design</b> <ul style="list-style-type: none"> <li>• Cross-sectional study: 10</li> <li>• Prospective observational: 4</li> <li>• Retrospective observational: 3</li> </ul>	<b>Study duration</b> <ul style="list-style-type: none"> <li>• Ranged from 8 months to 7 years</li> <li>• 6 studies did not report</li> </ul>	<b>Country of the first author</b> <ul style="list-style-type: none"> <li>• USA: 10</li> <li>• Germany: 2</li> <li>• Australia, Finland, France, Netherlands, Sweden: 1 each</li> </ul>	<b>Follow-up duration</b> <ul style="list-style-type: none"> <li>• Ranged from 6 months to 5 years</li> <li>• 8 studies did not report</li> </ul>
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## Registry Information

<b>Number of registries</b> <ul style="list-style-type: none"> <li>• 19 registries were reported in the 17 included studies</li> <li>• 14 studies: 1 registry</li> <li>• 1 study: 2 registries</li> <li>• 2 studies: 3 registries (same set in both studies)</li> </ul>	<b>Type of registry</b> <ul style="list-style-type: none"> <li>• Hospital-based registry, collective: 6</li> <li>• Hospital-based registry, single centre: 4</li> <li>• Population-based registry: 7</li> <li>• Not clear: 2</li> </ul>	<b>Country of registry</b> <ul style="list-style-type: none"> <li>• Registries from 8 different countries</li> <li>• USA: 11</li> <li>• Germany: 2</li> <li>• Australia, Denmark, Iceland, France, Netherlands, Sweden: 1 each</li> </ul>	<b>Year of launching the registry</b> <ul style="list-style-type: none"> <li>• Ranged from 2003-2012</li> <li>• 9 studies did not report</li> </ul>
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## Name of Registry

<b>USA</b> <ul style="list-style-type: none"> <li>• Breast Cancer Collaborative Registry (BCCR)</li> <li>• Breast Molecular Epidemiological Resource Core (BMER) data repository</li> <li>• California Cancer Registry (CCR) (2 studies)</li> <li>• Cancer Surveillance System (CSS) registry, not specified</li> <li>• Cancer Surveillance System (CSS) registry, Washington</li> <li>• Carolina Senior Registry (CSR)</li> <li>• City of Hope Cancer Registry (2 studies)</li> <li>• Pennsylvania Cancer Registry</li> <li>• Systemic Therapies for HER2-positive Metastatic Breast Cancer Study (SystHERs) registry</li> <li>• UCLA Cancer Registry (2 studies)</li> <li>• Academic medical center cancer registry (name not specified)</li> </ul>	<b>Germany</b> <ul style="list-style-type: none"> <li>• Network Oncology (NO) clinical registry, Germany</li> <li>• Tumour Registry Breast Cancer (TMK), Germany</li> </ul>	<b>Other countries</b> <ul style="list-style-type: none"> <li>• <b>Australia:</b> Victorian Cancer Registry, Victoria</li> <li>• <b>France:</b> Breast and Gynecologic Cancer Registry of the Côte d'Or</li> <li>• <b>Netherlands:</b> Southeast Netherlands Advanced Breast cancer (SONABRE) Registry</li> <li>• <b>Sweden:</b> Swedish National Quality Registry for Breast Cancer</li> <li>• <b>Denmark:</b> Cancer registry (not specified)</li> <li>• <b>Iceland:</b> Cancer registry (not specified)</li> </ul>
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## Population

### Demographics

- Sample size
  - Overall: 7,001
  - Range: 71-1260
- Age
  - Mean  $\pm$  SD: 34.6  $\pm$  4.1 years to 71.32  $\pm$  8.11 years (10 studies)
  - Median: 35 (range 22-39) years to 59 (IQR 50-69) years (3 studies)
  - 4 studies did not report
- Sex
  - All studies included only female breast cancer patients

### Type/ Stage of Breast Cancer

- Early breast cancer : 2 studies
- Non-metastatic Breast Cancer : 5 studies
- Breast cancer or ductal carcinoma in situ : 1 study
- Advanced breast cancer : 1 study
- Invasive breast cancer : 1 study
- HER2-positive Metastatic Breast Cancer : 1 study
- Young breast cancer survivors (YBCS) : 1 study
- All stages : 5 studies

## Intervention/Comparator Details

### Chemotherapeutic Agent Details

- Specified in 3 studies only:
  - Epirubicin, Paclitaxel, cyclophosphamide
  - Taxanes, Platinum compounds, Vinca derivative, Antimetabolite
  - Cyclophosphamide, Docetaxel, Paclitaxel, Epirubicin/ doxorubicin, Fluorouracil
- 14 studies did not specify the name of chemotherapeutic agents

### Comparator

- Only 2 studies had comparator arm:
  - Viscum album extract (1 study)
  - Intentional non-receivers of Chemotherapy/radiation therapy
- 15 studies did not have comparator

## PRO Information

### Number of PROs evaluated per study

- Most studies evaluated 1 or 2 PROs
- Number of PROs evaluated:
  - 1 PRO: 6 studies
  - 2 PROs: 5 studies
  - 3 PROs: 3 studies
  - 4 PROs: 2 study
  - 5 PROs: 1 study

### Type of PRO

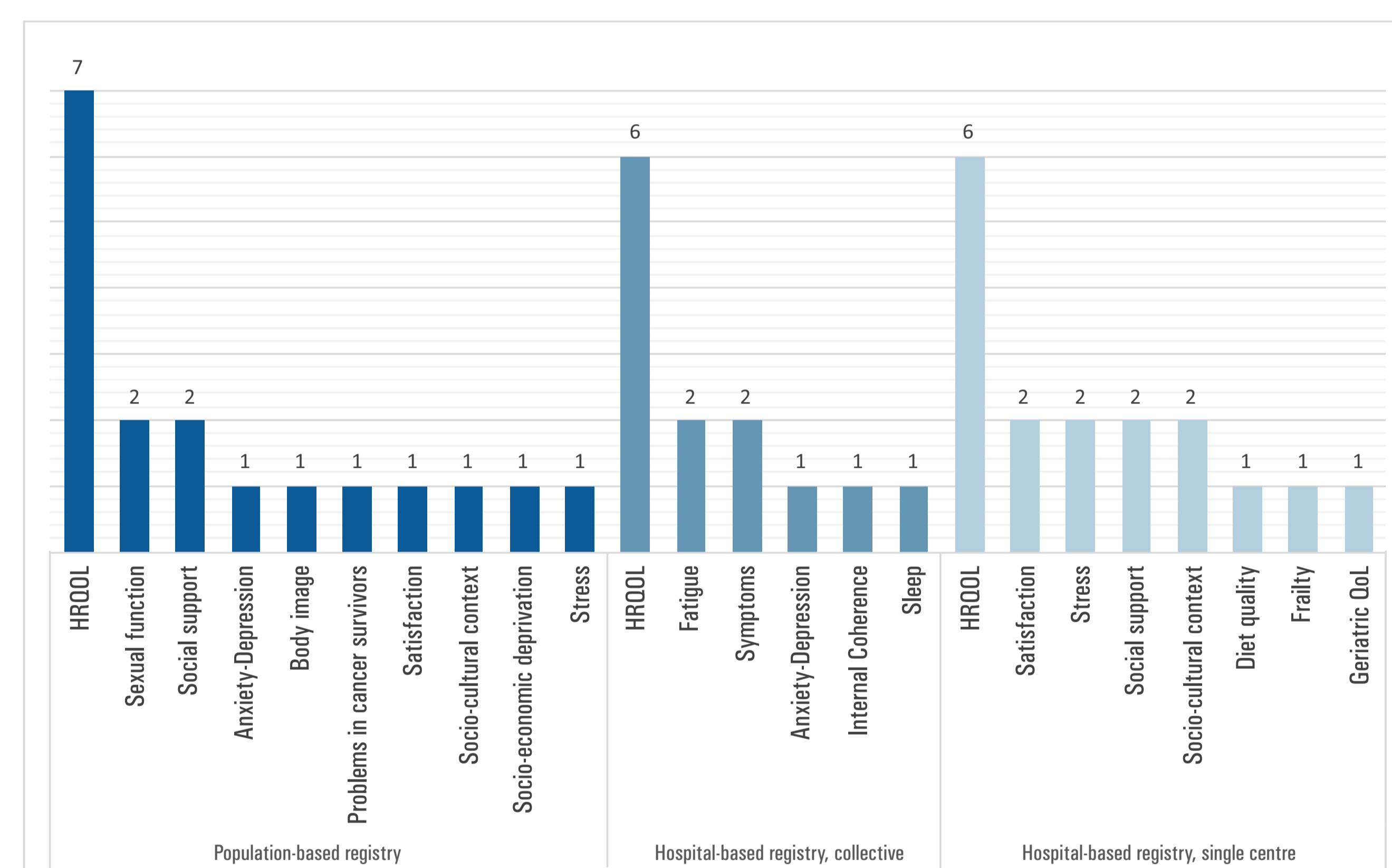
- A total of 17 different PROs were evaluated by the included studies
- Total evaluations: 44 PROs
  - HRQOL: 17 studies
  - Symptoms: 5 studies
  - Anxiety-Depression; Sexual function, Social support: 3 studies each
  - Fatigue: 2 studies
  - Body image, Diet quality, Frailty, Geriatric QoL, Internal Coherence, Problems in cancer survivors, Satisfaction, Sleep, Socio-economic deprivation, Socio-cultural context, Stress: 1 study each
- 36 different PRO scales were used
  - 20 scales had subscales; maximum: 11

### PRO changes over time

- Only 4 studies measured PROs in pairs for before-after comparison
- Significance of PRO changes over time documented by only one study

## Type of Registry vs Type of PRO

- Population-based registry had more PRO types
- HRQoL was the most frequent type of PRO recorded in all type of registries



## Discussion

- Most registries focused on epidemiology and treatment outcomes; PROs were reported in only a few registry analyses
- HRQOL was the most frequently measured PRO
- The most frequently used PRO scales were SF-36 (4 studies); FACT-B, FACT-G, and HADS (3 studies each)
- Cancer Problems in Living Scale had 11 subscales
- Before-after comparisons were performed in only 4 studies, and the results were not consistent
- There was a large amount of variation in the measurement of PROs in terms of frequency, subscales, and reporting
- Changes in PROs with different chemotherapeutic agents could not be evaluated because of inadequate data

## Limitations

- Search was limited to PubMed; databases like Embase were not searched
- Search was restricted to publications in English language only
- Male breast cancer cases were not included

## Conclusion

- Recording and analyzing PROs in breast cancer registry audit papers is inadequate and has a large amount of variation

## References

1. NCI. SEER Training Modules. Types of registries. <https://training.seer.cancer.gov/registration/types/>
2. Pereira I, Pereira M, Leite A, Pereira MG. Quality of Life in Women With Breast Cancer Receiving Chemotherapy and the Moderating Role of Cortisol. Cancer Nurs. 2022; Mar 24.