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[1]
- 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)[2]
- 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	• Humans suffering from any stage and form of breast cancer • No restrictions on age, gender, race, stage, immuno histological type	• Humans without breast cancer • No human subjects
Intervention	• Chemotherapy, either alone or in combination with other modalities of breast cancer treatment (immunotherapy, endocrine therapy, surgery, radiotherapy etc)	• Chemotherapy not used in breast cancer treatment
Comparator	• Any comparator	• No restriction
Outcome	• PROs: quality of life, patient satisfaction, all other PROs	• All other outcomes
Study design	• Analysis of some type of registries (disease, cancer, population, hospital, etc)	• All other types of papers
Databases	• PubMed	
Date range	• Published in the last decade (from 01 Jan 2012 till date)	Older papers

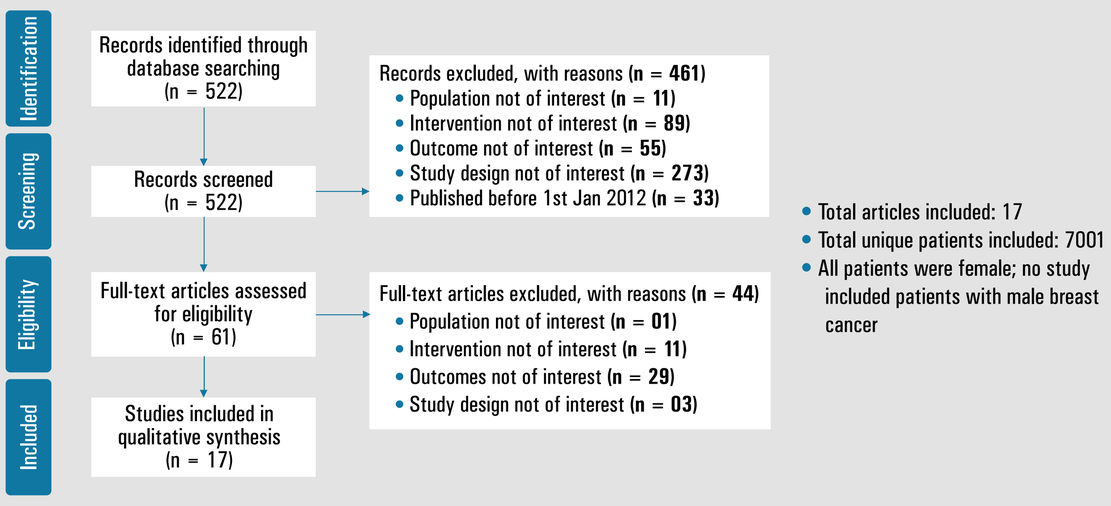
PubMed Search Strategy

From 1st Jan 2012 till 21st June 2022

No	Terms	Hits	Facet
#1	"Registries" [MeSH Terms] OR "Registry" [All Fields] OR "Registries" [All Fields] OR "Population Register" [All Fields] OR "Population Registers" [All Fields] OR "Parish Registers" [All Fields] OR "Parish Register" [All Fields] OR "Patient registry" [All Fields] OR "patient registries" [All Fields]	223,642	All registry studies
#2	"Breast Neoplasms" [MeSH Terms] OR "breast cancer" [All Fields] OR "Breast Neoplasm" [All Fields] OR "Breast Tumor" [All Fields] OR "Breast Tumour" [All Fields] OR "Mammary Cancer" [All Fields] OR "Mammary Carcinoma" [All Fields] OR "Mammary Neoplasm" [All Fields] OR "Breast Carcinoma" [All Fields] OR "mammary tumor" [All Fields] OR "mammary tumour " [All Fields]	437,817	All publications about breast cancer
#3	"Patient Reported Outcome Measures"[MeSH Terms] OR "Quality of Life" [MeSH Terms] OR "Quality of Life"[All Fields] OR "patient reported outcome"[All Fields] OR qol "[All Fields] OR "HRQOL"[All Fields]	713,733	All studies reporting PROs, QoL, or HRQoL
#4	#1 AND #2 AND #3	522	All registry studies about breast cancer reporting PROs

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

Results



- Total articles included: 17
- Total unique patients included: 7001
- All patients were female; no study included patients with male breast cancer

Publication Information

Study design
- Cross-sectional study: 10
- Prospective observational: 4
- Retrospective observational: 3

Study duration
- Ranged from 8 months to 7 years
- 6 studies did not report

Country of the first author
- USA: 10
- Germany: 2
- Australia, Finland, France, Netherlands, Sweden: 1 each

Follow-up duration
- Ranged from 6 months to 5 years
- 8 studies did not report

Registry Information

Number of registries
- 19 registries were reported in the 17 included studies
- 14 studies: 1 registry
- 1 study: 2 registries
- 2 studies: 3 registries (same set in both studies)

Type of registry
- Hospital-based registry, collective: 6
- Hospital-based registry, single centre: 4
- Population-based registry: 7
- Not clear: 2

Country of registry
- Registries from 8 different countries
- USA: 11
- Germany: 2
- Australia, Denmark, Iceland, France, Netherlands, Sweden: 1 each

Year of launching the registry
- Ranged from 2003-2012
- 9 studies did not report

Name of Registry

USA
- Breast Cancer Collaborative Registry (BCCR)
- Breast Molecular Epidemiological Resource Core (BMER) data repository
- California Cancer Registry (CCR) **(2 studies)**
- Cancer Surveillance System (CSS) registry, not specified
- Cancer Surveillance System (CSS) registry, Washington
- Carolina Senior Registry (CSR)
- City of Hope Cancer Registry **(2 studies)**
- Pennsylvania Cancer Registry
- Systemic Therapies for HER2-positive Metastatic Breast Cancer Study (SystHERs) registry
- UCLA Cancer Registry **(2 studies)**
- Academic medical center cancer registry (name not specified)

Germany
- Network Oncology (NO) clinical registry, Germany
- Tumour Registry Breast Cancer (TMK), Germany

Other countries
- **Australia:** Victorian Cancer Registry, Victoria
- **France:** Breast and Gynecologic Cancer Registry of the Côte d'Or
- **Netherlands:** Southeast Netherlands Advanced Breast cancer (SONABRE) Registry
- **Sweden:** Swedish National Quality Registry for Breast Cancer
- **Denmark:** Cancer registry (not specified)
- **Iceland:** Cancer registry (not specified)

Population

Demographics
- Sample size
  - Overall: 7,001
  - Range: 71-1260
- **Age**
  - **Mean ± SD**: 34.6 ± 4.1 years to 71.32 ±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

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 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

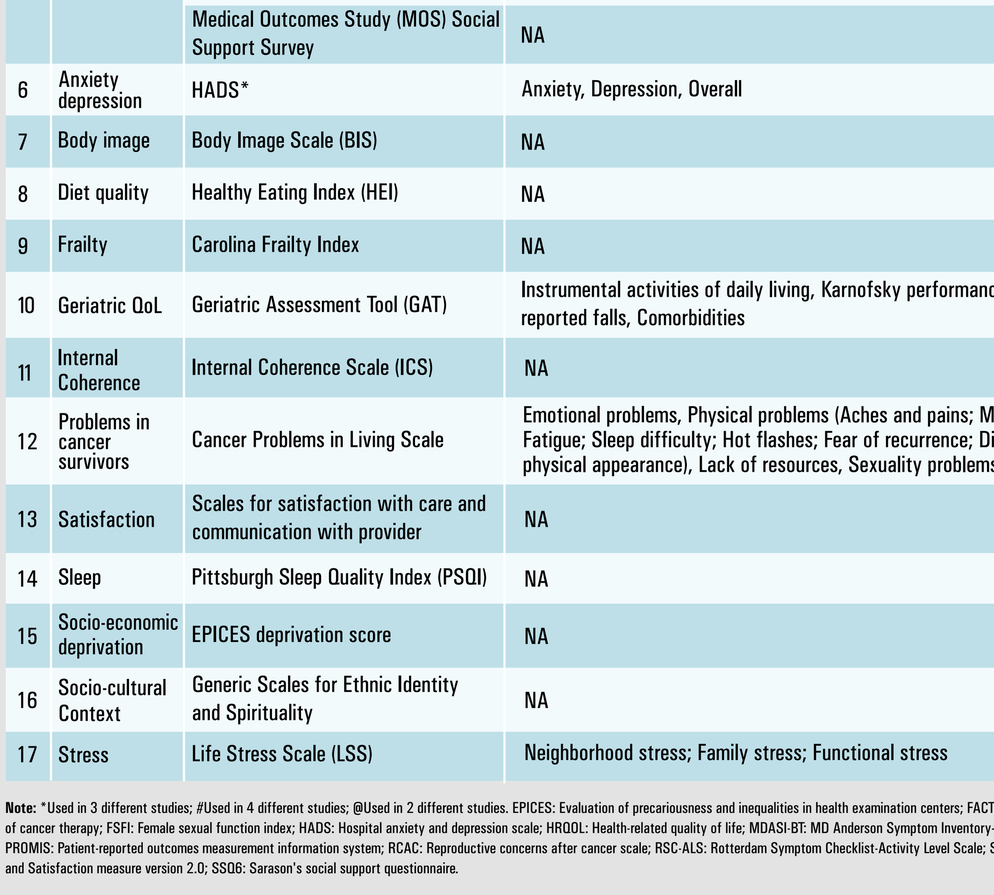
PROs: Scales and Subscales

No	Name of PRO	Scales used	Subscales
1	HRQOL	RAND-36	Emotional, Social
		FACT - Breast (FACT-B)*	Shortness of breath, Dress consciousness, Arm swelling, Sexual attractiveness, Hair loss, Family, Stress, Weight, Pain
		FACT-B Trial Outcome Index (TOI)	NA
		FACT-Global (FACT-G)*	Emotional, Functional, Social/ family, Physical, Overall score
		PROMIS	Physical Function, Social Roles, Fatigue, Depression, Anxiety, Pain Interference, Sleep Disturbance
		Short Form -12 (SF-12)	General health, Physical functioning, Role physical, Role emotional, Bodily pain, Mental health, Vitality, Social functioning
		Short Form-36 (SF-36)#	General health, Physical functioning, Role physical, Role emotional, Bodily pain, Mental health, Vitality, Social functioning
		EQ-5D-3L	Mobility, Self-care, Usual activities, Pain/discomfort, Anxiety/ depression
		EQ-5D-5L	Mobility, Self-care, Usual activities, Pain/discomfort, Anxiety/ depression
		EORTC QLQ-C30@	NA
2	Symptoms	RSC-ALS	NA
		MDASI-BT	Cognitive functions, interference in daily life
		FACT-Taxane (FACT-T)	NA
		FACT-Endocrine Symptoms (FACT-ES)	NA
		EORTC QLQ-BR23	Body image, Future perspective, Sexual functioning, Sexual enjoyment, Systemic therapy side effects, Breast symptoms, Arm symptoms, Upset by hair loss
3	Sexual function	FSFI	Desire, Arousal, Pain, Satisfaction, Lubrication, Orgasm, Global Score
		SexFS	Lubrication, discomfort (overall, clitoral, labia), satisfaction with sexual life
		RCAC	Fertility potential, Partner disclosure, Child's health, Personal health, Acceptance, Becoming pregnant
4	Fatigue	Cancer Fatigue Scale (CFS-D)	NA
		Brief Fatigue Inventory (BFI)	Fatigue intensity, Fatigue interference, Total score
5	Social support	SSQ6	Availability, satisfaction
		Structural-Functional Social Support Scale	Support from supervisor, from colleagues
		Medical Outcomes Study (MOS) Social Support Survey	NA
6	Anxiety depression	HADS*	Anxiety, Depression, Overall
7	Body image	Body Image Scale (BIS)	NA
8	Diet quality	Healthy Eating Index (HEI)	NA
9	Frailty	Carolina Frailty Index	NA
10	Geriatric QoL	Geriatric Assessment Tool (GAT)	Instrumental activities of daily living, Karnofsky performance status, Self reported falls, Comorbidities
11	Internal Coherence	Internal Coherence Scale (ICS)	NA
12	Problems in cancer survivors	Cancer Problems in Living Scale	Emotional problems, Physical problems (Aches and pains; Muscle stiffness; Fatigue; Sleep difficulty; Hot flashes; Fear of recurrence; Discomfort with physical appearance), Lack of resources, Sexuality problems
13	Satisfaction	Scales for satisfaction with care and communication with provider	NA
14	Sleep	Pittsburgh Sleep Quality Index (PSQI)	NA
15	Socio-economic deprivation	EPICES deprivation score	NA
16	Socio-cultural Context	Generic Scales for Ethnic Identity and Spirituality	NA
17	Stress	Life Stress Scale (LSS)	Neighborhood stress; Family stress; Functional stress

Note: *Used in 3 different studies; #Used in 4 different studies; @Used in 2 different studies. EPICES: Evaluation of precariousness and inequalities in health examination centers; FACT: Functional assessment of cancer therapy; FSFI: Female sexual function index; HADS: Hospital anxiety and depression scale; HRQOL: Health-related quality of life; MDASI-BT: MD Anderson Symptom Inventory-Brain Tumor Module; PROMIS: Patient-reported outcomes measurement information system; RCAC: Reproductive concerns after cancer scale; RSC-ALS: Rotterdam Symptom Checklist-Activity Level Scale; SexFS: Sexual Function and Satisfaction measure version 2.0; SSQ6: Sarason's social support questionnaire.

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 Â, Pereira MG. Quality of Life in Women With Breast Cancer Receiving Chemotherapy and the Moderating Role of Cortisol. Cancer Nurs. 2022 Mar 24.

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