RWD127

Feasibility of Constructing HR+/HER2– Metastatic Breast Cancer Cohorts Incorporating Treatment Sequencing in a Japanese Multicentre Oncology EMR Database

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Background

- Endocrine therapy (ET) combined with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors is a standard treatment option for hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2–) advanced or metastatic breast cancer (BC).
- Japanese real-world studies have described treatment patterns and outcomes among patients receiving CDK4/6 inhibitors. However, claims-based studies often have limited access to biomarker results, laboratory values, and detailed treatment pathways.
- J-CONNECT is a Japanese multicentre oncology database linking hospital-based cancer registry data with electronic medical records (EMRs), including treatment, laboratory, and selected biomarker information.

Objectives

- **To assess the feasibility of constructing biomarker-defined HR+/HER2– metastatic breast cancer cohorts incorporating treatment sequencing, including ET exposure and CDK4/6 inhibitor use, in J-CONNECT.**

Methods

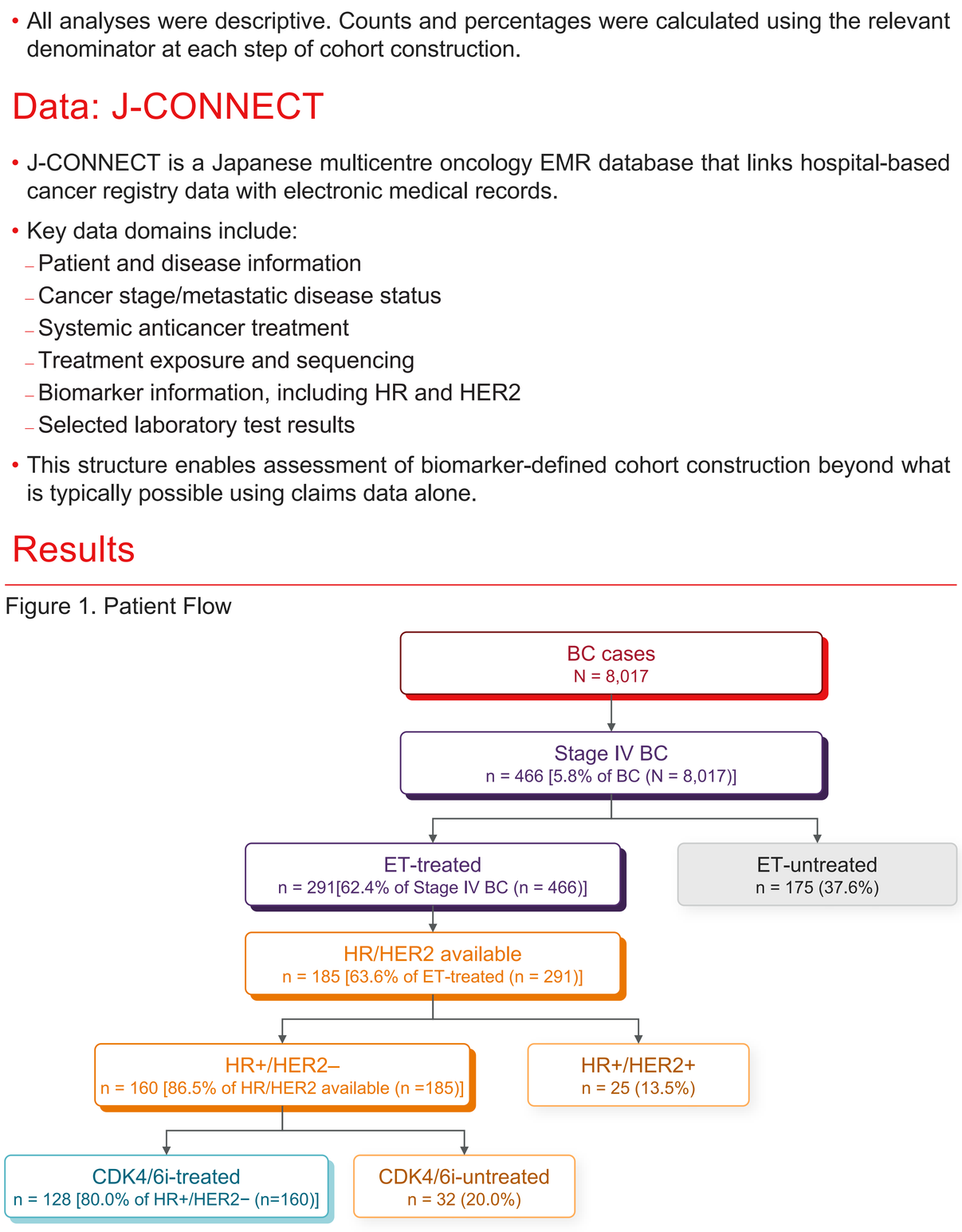
- We conducted a retrospective feasibility assessment using J-CONNECT data from seven participating institutions. The analysis included patients diagnosed with breast cancer between 2018 and 2023 and used data available through May 2026.
- Sequential cohort construction was performed for:
  - Breast cancer cases, Stage IV/metastatic breast cancer, ET-treated patients, HR+/HER2– defined subgroups, CDK4/6 inhibitor-treated or untreated cohorts
- Feasibility domains included:
  - HR/HER2 availability, treatment exposure, treatment sequencing, selected baseline laboratory variables
- All analyses were descriptive. Counts and percentages were calculated using the relevant denominator at each step of cohort construction.

Data: J-CONNECT

- J-CONNECT is a Japanese multicentre oncology EMR database that links hospital-based cancer registry data with electronic medical records.
- Key data domains include:
  - Patient and disease information
  - Cancer stage/metastatic disease status
  - Systemic anticancer treatment
  - Treatment exposure and sequencing
  - Biomarker information, including HR and HER2
  - Selected laboratory test results
- This structure enables assessment of biomarker-defined cohort construction beyond what is typically possible using claims data alone.

Results

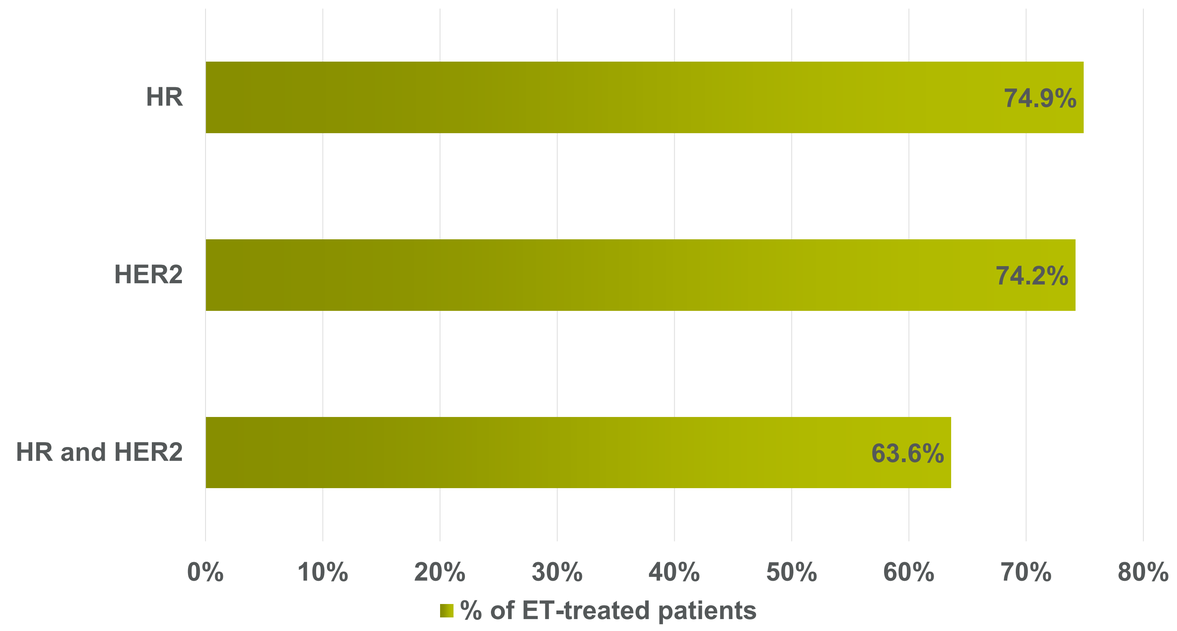
Figure 1. Patient Flow



J-CONNECT enabled sequential identification of HR+/HER2– metastatic breast cancer and CDK4/6 inhibitor-treated cohorts. Biomarker and baseline laboratory data were available for a substantial proportion of eligible patients.
Abbreviations: BC = breast cancer; CDK4/6 = cyclin-dependent kinase 4/6; ET = endocrine therapy; HR+/HER2– = hormone receptor-positive, human epidermal growth factor receptor 2-negative

Results (cont.)

Figure 2. Biomarker Availability



Abbreviations: ET = endocrine therapy; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2

Table 1. Feasibility Summary

Definition	N	%	Denominator
Breast cancer cases	8,017	–	–
Stage IV / metastatic disease	466	5.8	Breast cancer cases
ET-treated	291	62.4	Stage IV/metastatic disease
HR status available	218	74.9	ET-treated patients
HER2 status available	216	74.2	ET-treated patients
Both HR and HER2 status available	185	63.6	ET-treated patients
HR+/HER2–	160	86.5	HR/HER2 classifiable patients
HR+/HER2+	25	13.5	HR/HER2 classifiable patients
CDK4/6 inhibitor-treated	128	80.0	ET-treated HR+/HER2− patients
CDK4/6 inhibitor-untreated	32	20.0	ET-treated HR+/HER2− patients
At least one selected baseline laboratory value available	118	92.2	ET-treated HR+/HER2− CDK4/6 inhibitor-treated patients
AST/ALT baseline laboratory value available	118	92.2	ET-treated HR+/HER2− CDK4/6 inhibitor-treated patients
Creatinine/eGFR baseline laboratory value available	115	89.8	ET-treated HR+/HER2− CDK4/6 inhibitor-treated patients

Abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase; BC = breast cancer; CDK4/6 = cyclin-dependent kinase 4/6; eGFR = estimated glomerular filtration rate; ET = endocrine therapy; HR+/HER2− = hormone receptor-positive, human epidermal growth factor receptor 2-negative

Conclusions

- **J-CONNECT can support construction of clinically meaningful biomarker-defined metastatic breast cancer cohorts incorporating treatment sequencing, including CDK4/6 inhibitor use, in Japan.**
- **These findings position J-CONNECT as a clinically detailed RWD platform for evaluating precision oncology research feasibility beyond what is typically possible using claims data alone.**
- **Study-specific assessment of biomarker completeness, laboratory availability, and outcome ascertainment remains necessary for future comparative or safety studies.**

References

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