

Background

- Breast cancer is the most common cancer in women and second overall in Norway ¹. Hormone receptor positive (HR+) breast cancer, the most common form of breast cancer in Norway, is generally treated with endocrine therapy ^{2,3}
- Abemaciclib was approved by the European Medicines Agency (EMA) in 2018 for HR+, HER2- (human epidermal receptor 2 negative) locally advanced/metastatic breast cancer in combination with endocrine therapies. In 2022, EMA approved the early breast cancer indication for abemaciclib based on monarchE trial.
- Lilly's monarchE phase 3 trial investigated abemaciclib in combination with endocrine therapy as treatment for HR+, HER2-node-positive, high risk, early breast cancer and has demonstrated improvement in invasive disease free survival ⁴

Objective

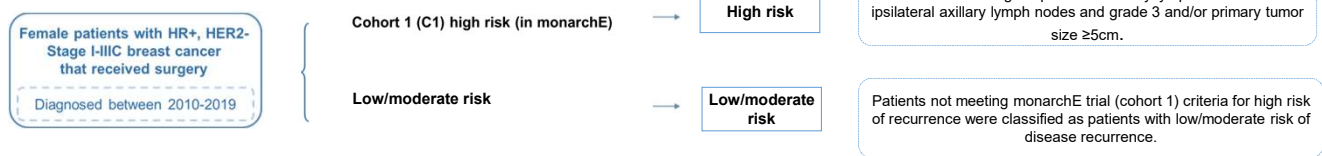
- To assess the percent and demographic and clinical characteristics of female patients in Norway with early breast cancer (EBC) with high-risk of disease recurrence, who met the high-risk criteria in monarchE (cohort 1), a Ph3 trial of abemaciclib for the adjuvant treatment of HR+, HER2-, node-positive, high-risk, early breast cancer.

Study Design/Methods

Methods:

- Observational retrospective study:** data from the national Norwegian Breast Cancer Register
- Statistical analysis:** descriptive statistics and survival rate estimated using Kaplan-Meier curve
- Exclusion criteria:** breast cancer diagnosis at autopsy

Figure 1. EBC Patient population and groups



Results

Size of populations and demographic characteristics

Total population=20,632 patients

Figure 2. Size of patient groups

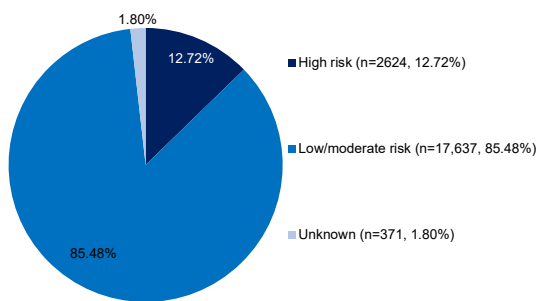
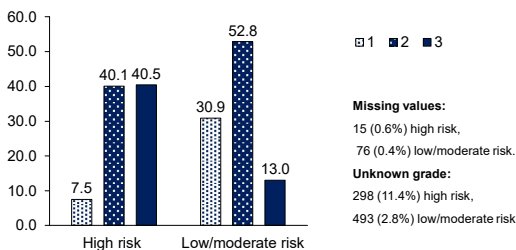


Table 1. Diagnosed cases per year and age at diagnosis

	High risk	Low/moderate risk
	Mean (SD)	Mean (SD)
Diagnosed cases	262 (22.9)	1,764 (269.5)
Age	59 (14)	61 (12)

Figure 5. Tumor grade



Clinical characteristics

Figure 3. Breast cancer stage

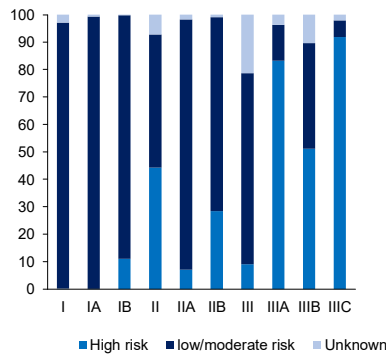


Figure 4. Number of positive lymph nodes at surgery

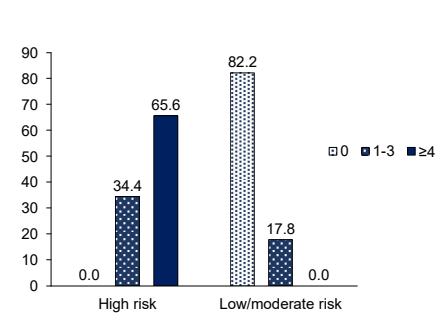


Figure 7. 5-years overall survival

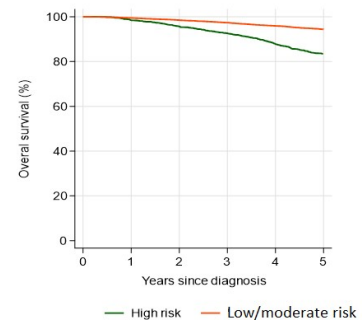
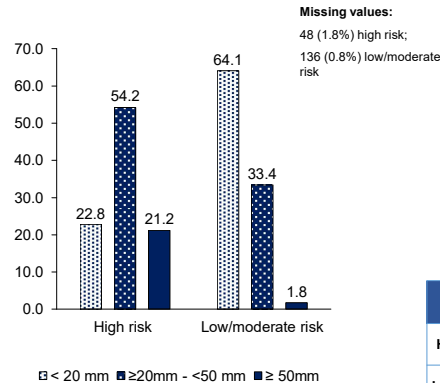


Figure 6. Tumor size



Conclusions

- A total of 20,632 HR+, HER2- early breast cancer female patients were diagnosed in Norway between 2010 and 2019. 2,624 (12.7%) of them met the inclusion criteria for cohort 1 high risk of recurrence used in the monarchE trial and are likely to benefit from novel treatment strategies targeted for patients with a high risk of disease recurrence.
- monarchE-like high-risk population accounted for most stage III cancers and presented increased tumor size. All cohort 1 high risk patients had at least one positive lymph node at surgery, while a high percentage of the low/moderate risk population did not show any positive lymph node (82.18%). No patients in not-high risk population had LN ≥ 4.
- The 5-year overall survival rate was significantly lower in the monarchE-like cohort 1 high risk population compared to the low/moderate risk population (83.49% vs 94.34%; p<0.0001).

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- Johansson, A. L., et al. (2019). Breast cancer-specific survival by clinical subtype after 7 years follow-up of young and elderly women in a nationwide cohort. International journal of cancer, 144(6), 1251-1261.
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