P016

# Patient Characteristics, Treatment Patterns and Long-term Outcomes from a Real-World Population of Early Breast Cancer Patients at High Risk of Recurrence in Scotland

**Peter S Hall[1], Giovanni Tramonti[1], Michael Rañopa[2], Mahéva Vallet[1], Rosalind Jarvis[2], Waleed Badreldin[2]**

[1]University of Edinburgh, Edinburgh, UK; [2]Eli Lilly and Company Ltd, Basingstoke, UK

## BACKGROUND

- Despite adjuvant endocrine treatment (AET) advances, node-positive, hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2−) early breast cancer (EBC) is associated with a considerable risk of recurrence[1]
- monarchE, a randomized phase III clinical trial testing the combination of AET with abemaciclib for 2 years, demonstrated improved Invasive Disease-Free Survival (IDFS) compared to AET alone in patients (pts) with high risk node-positive HR+ HER2− EBC[2]
- To date, real-world data regarding high risk HR+ HER2− EBC per monarchE criteria include:
  - a US population study of stage I-III, both node-negative and node-positive HR+ HER2− EBC (diagnosed 2011–2020; high risk: 14% of overall study population)[3]
  - a German single-centre study of both node-negative and node-positive EBC (surgically treated 2018–2020; HR+ HER2− EBC 76% of overall study population; high risk: 19% of HR+ HER2− EBC)[4]

**High Risk Criteria in monarchE, Cohort 1**
(91% of study population)[2]

· ≥4 pathologically positive axillary lymph nodes (pALNs)
***OR***
· 1−3 pALNs
***and at least one*** of the following:
- primary invasive tumour size ≥5cm
- tumour histological grade 3

## OBJECTIVE

### Primary Objective:

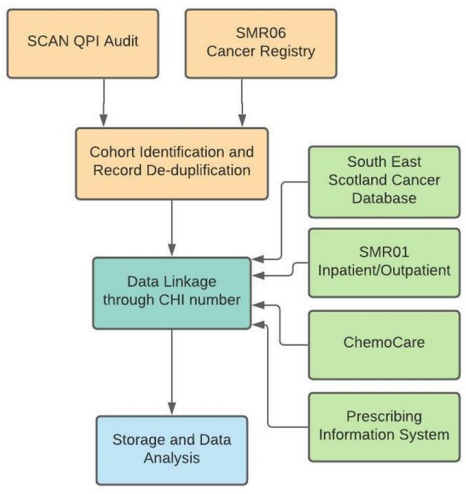
To describe the demographic/clinical characteristics in pts with node-positive HR+, HER2− EBC who are at high risk of recurrence [as per monarchE Cohort 1 high risk criteria (hRisk)] in the region of Scotland served by the Edinburgh Cancer Centre, a specialist referral centre

### Secondary Objectives:

- Describe the treatment patterns on historic standard of care for this patient population in a real-world setting in Scotland
- Describe outcomes [IDFS and overall survival (OS) up to 10 years], both at cohort level as well as in disease and patient subgroups
- Estimate the healthcare resource utilisation

## STUDY DESIGN

### National Health Service Lothian data sources* were utilised




Data analysis (with follow up until 1st August 2021) included:
- Patient demographic and clinical characteristics
- Treatment patterns
- IDFS and OS (up to 10 years)
- Healthcare utilisation

1. SCAN QPI audit: National Cancer Quality Steering Group, develops small sets of tumour specific national quality performance indicators (QPI) since 2008
2. Scottish Cancer Registry SMR06 (Socrates): main database of the Scottish Cancer Registry, collects data since 1958
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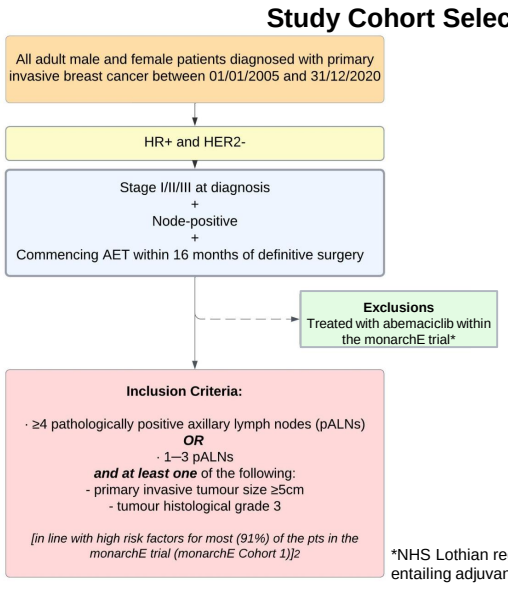


- Men and women with first breast cancer, aged 18 and over, were identified based on the most recent chronological record of diagnosis code (Cancer Registry incidence) ICD-10 C50.X for the unique patient identifier
- In the case of multiple simultaneous records (duplicates or multiple same-date cancer), the record with the most complete data and highest risk disease factors were selected
- HER2− is defined as HER2 0 or 1+ by immunohistochemistry or 2+ and not amplified on FISH. HR+ defined as either/or Estrogen (ER) / Progesterone (PR) positive, where positive is Allred score >2
- ER/PR low is Allred score of 3 or 4 and were also included as a subgroup of the study population

*NHS Lothian region did not participate in most of the other trials entailing adjuvant cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors

## KEY RESULT

### Patient characteristics at diagnosis

- **1498 hRisk** pt records were identified in the study, with a **median follow-up of 6.0 years**
- 99.1% were female
- Median age 59 years (range: 24-93) (vs 51 years in monarchE Cohort 1)[2,5]
- The majority of pts were postmenopausal (71.5% vs 56.6% in monarchE Cohort 1)[2,5]
- 81.6% of pts were from urban areas
- Mean Body Surface Area (BSA) was 1.82 $m^2$
- A high proportion (70.5%) of hRisk pts had a Charlson Comorbidity Index (CCI) of 0

**Menopausal status and CCI at diagnosis**

| Cohorts | hRisk (n=1498) | |
|---|---|---|
| | n | % |
| **Menopausal Status** | | |
| **Pre/Peri** | 427 | 28.5 |
| **Post** | 1071 | 71.5 |
| **Charlson Comorbidity Index** | | |
| **0** | 1056 | 70.5 |
| **1** | 33 | 2.2 |
| **2** | <10 | <0.7 |
| **3+** | <10 | <0.7 |
| **NA** | >389 | >26 |

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### Disease characteristics at diagnosis

- According to histopathological evaluation following surgery in pts who did not receive neoadjuvant chemotherapy (n=1125):
  - 52.1% had ≥4 pALNs
  - 27.6% had tumour size ≥5cm
- More than half (>57.4%) of all pts with hRisk disease had a grade 3 tumour
- Most pts (62.3%) with hRisk features had AJCC stage 2 disease

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**Disease characteristics at diagnosis**

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| **Pathological Tumour Size (in population not given neoadjuvant chemotherapy) (n: 1125)** | | |
| **<20mm** | 257 | 22.8 |
| **20-50mm** | 539 | 47.9 |
| **>50mm** | 310 | 27.6 |
| **Missing** | 19 | 1.7 |
| **Number of pALNs (in population not given neoadjuvant chemotherapy) (n: 1125)** | | |
| **0** | 0 | 0 |
| **1-3** | 539 | 47.9 |
| **4-9** | 393 | 34.9 |
| **10+** | 193 | 17.2 |
| **Missing** | 0 | 0 |
| **Tumour Grade (n: 1498)** | | |
| **1** | 36 | 2.4 |
| **2** | 592 | 39.5 |
| **3** | >860 | >57.4 |
| **Unknown** | <10 | <0.7 |
| **AJCC stage (n: 1498)** | | |
| **1** | 214 | 14.3 |
| **2** | 933 | 62.3 |
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| **3C** | 15 | 1.0 |
| **X** | 46 | 3.1 |

## RESULTS -Treatment

- Adjuvant therapy mostly involved combination anthracycline and taxane-based chemotherapy
- Missing data on ET limits interpretation
- Radiotherapy was mainstay (92.1%)

**Treatment modalities**

| Cohorts | hRisk (n=1498) | |
|---|---|---|
| | n | % |
| **Chemotherapy (n: 1498)** | | |
| **Neoadjuvant only** | 123 | 8.2 |
| **Adjuvant only** | 654 | 43.7 |
| **Both neoadjuvant and adjuvant** | 250 | 16.7 |
| **NA** | 471 | 31.4 |
| **Adjuvant Endocrine Therapy (all) (n: 1498)** | | |
| **Anastrozole** | 99 | 6.6 |
| **Exemestane** | <10 | <0.7 |
| **Letrozole** | 516 | 34.4 |
| **Tamoxifen** | 273 | 18.2 |
| **Unspecified** | >600 | >40 |
| **Ovarian Function Suppression (n: 1498)** | | |
| **Goserelin** | 124 | 8.3 |
| **NA** | 1374 | 91.7 |
| **Radiotherapy (n: 1498)** | | |
| **Received** | 1380 | 92.1 |
| **NA** | 118 | 7.9 |

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## RESULTS -Treatment

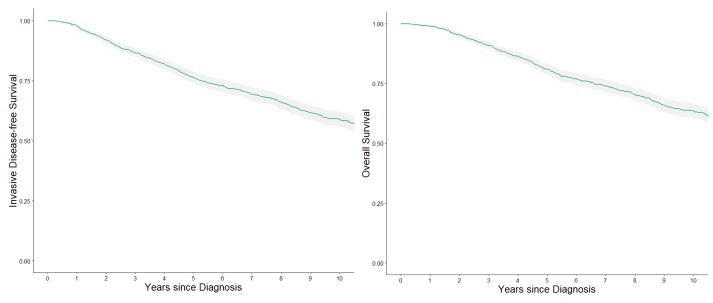
**Time from diagnosis to different treatment modalities**

| Cohorts | hRisk (n=1498) | |
|---|---|---|
| | Mean | SD |
| **Time from Diagnosis to First Chemotherapy (n: 1027)** | | |
| **Time (days)** | 80.9 | 64.2 |
| **Time from Diagnosis to Surgery (n: 1498)** | | |
| **Time (days)** | 87.7 | 171.9 |
| **Time from Diagnosis to Radiotherapy (n: 1380)** | | |
| **Time (days)** | 215.0 | 89.9 |

- Mean time from diagnosis to surgery and radiotherapy was 87.7 and 215 days, respectively
- 196/1498, 13.1% of pts with hRisk disease experienced a recurrence
- Median time from diagnosis to cancer recurrence was 33.9 months

SD: Standard Deviation

### IDFS* and OS

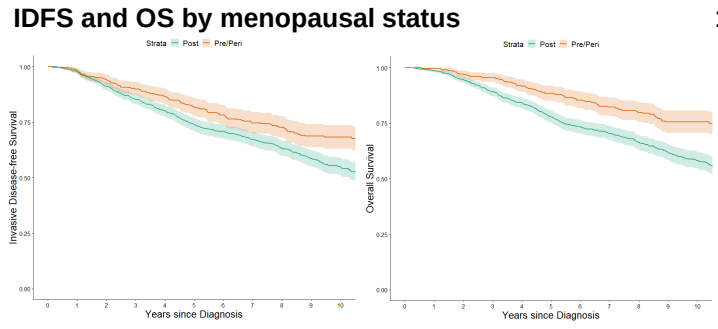



### IDFS* and OS (hRisk)

| | hRisk (n=1498) |
|---|---|
| **IDFS %** | |
| 2-year | 92 |
| 5-year | 76 |
| 10-year | 59 |
| **OS %** | |
| 2-year | 95 |
| 5-year | 81 |
| 10-year | 63 |

*IDFS was defined as per STEEP 2007 criteria

### IDFS and OS by menopausal status

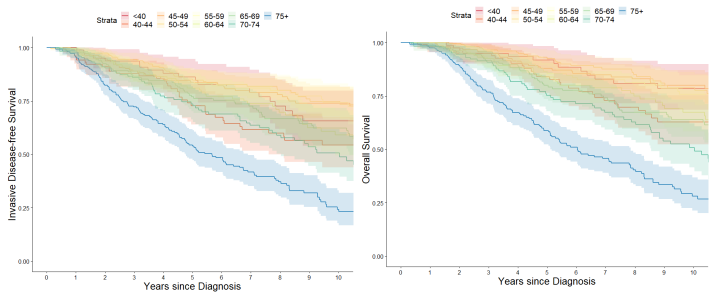



### 10-year IDFS and OS by menopausal status

| | hRisk (n=1498) | |
|---|---|---|
| **Menopausal status** | **10-year IDFS %** | **10-year OS %** |
| **Pre/Peri** (n=427) | 68 | 76 |
| **Post** (n=1071) | 55 | 58 |

- 10-year IDFS and OS were adversely affected by postmenopausal status

### IDFS and OS by age group

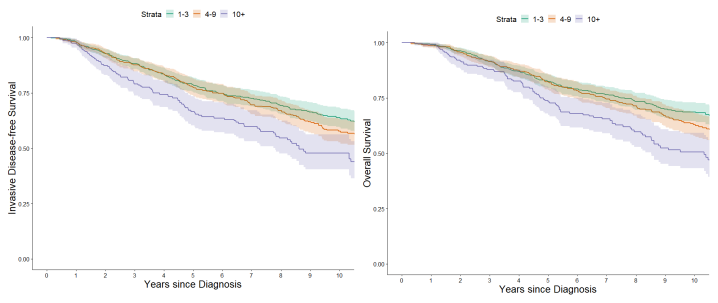



### 10-year IDFS and OS by age group

| | hRisk (n=1498) | |
|---|---|---|
| **Age group (years)** | **10-year IDFS %** | **10-year OS %** |
| <40 (n=84) | 66 | 78 |
| 40-44 (n=103) | 54 | 63 |
| 45-49 (n=192) | 74 | 80 |
| 50-54 (n=234) | 75 | 79 |
| 55-59 (n=161) | 74 | 76 |
| 60-64 (n=160) | 59 | 67 |
| 65-69 (n=165) | 62 | 64 |
| 70-74 (n=156) | 51 | 51 |
| ≥75 (n=243) | 24 | 28 |

- 10-year IDFS and OS were adversely affected by age ≥70 years

### IDFS and OS by number of pALNs



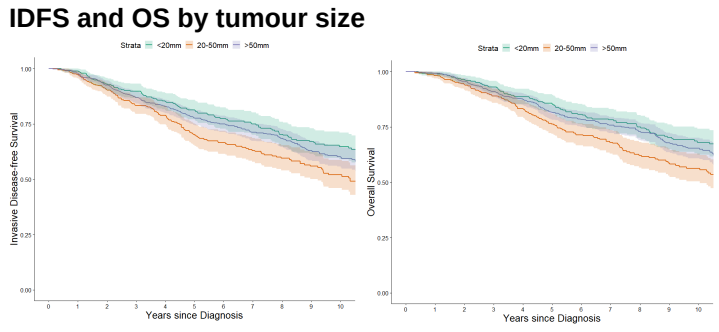

### 10-year IDFS and OS by number of pALNs

| | hRisk (n=1498) | |
|---|---|---|
| **Number of pALNs** | **10-year IDFS %** | **10-year OS %** |
| **0* (n: 0)** | N/A | N/A |
| **1-3 (n: 721)** | 64 | 69 |
| **4-9 (n: 535)** | 58 | 63 |
| **10+ (n: 242)** | 48 | 51 |

* 0 refers to clinically negative (node pathological positivity was required by protocol)

- Both 10-year IDFS and OS were adversely affected by increasing burden of nodal disease

### IDFS and OS by tumour size

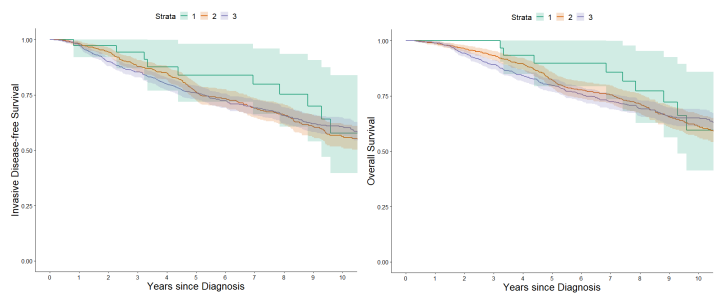



### 10-year IDFS and OS by tumour size

| | hRisk (n=1498) | |
|---|---|---|
| **Tumour size (mm)** | **10-year IDFS %** | **10-year OS %** |
| **<20 (n: 351)** | 65 | 68 |
| **20-50 (n: 702)** | 60 | 65 |
| **>50 (n: 405)** | 52 | 56 |

- Both 10-year IDFS and OS were adversely affected by increasing tumour size

### IDFS and OS by tumour grade




### 10-year IDFS and OS by tumour grade

| | hRisk (n=1498) | |
|---|---|---|
| **Tumour grade** | **10-year IDFS %** | **10-year OS %** |
| **Grade 1 (n: 36)** | 58 | 60 |
| **Grade 2 (n: 592)** | 56 | 61 |
| **Grade 3 (n: >860)** | 61 | 65 |

- Increasing tumour grade was not associated with worse survival outcomes

### Health care resource utilisation*

- Overall, mean number of inpatient admissions and outpatient visits in the first 2 years following diagnosis were 2.3 (SD 2.17) and 7.1 (SD 7.20), respectively
- For inpatient admissions, mean cumulative length of stay (per patient) and average length of stay (per admission per patient) in the first 2 years following diagnosis was 10.8 (SD 18.34) and 4.9 (SD 8.45) days, respectively

*Values were calculated only for patients that had at least one record

## LIMITATIONS

- Additional high risk features not captured here due to study design may also have affected outcomes
- This study population represents a historical cohort (2005-2021), thus outcomes need to be interpreted with caution if drawing conclusions with current practices
- In order to minimise the effect or bias from clinical trial participants within this study, exclusion of pts treated with abemaciclib within the monarchE trial was applied; the study region did not participate in most of the other major adjuvant CDK4/6i trials
- Baseline demographic differences compared to the monarchE trial, e.g. higher median age and higher post-menopausal women representation, may be attributed to real-world population versus clinical trial selection biases
  - Indeed, the German real-world study of both node-negative and node-positive EBC reported a proportion of pts with HR+ HER2− EBC being post-menopausal which is nearly identical to our study (71.9% vs 71.5%, respectively)[4]

## CONCLUSIONS

- Approximately half of pts with hRisk disease (52.1%) had ≥4 pALNs and more than a quarter (27.6%) had tumour size ≥5cm
- Nearly a quarter of pts with hRisk disease received neoadjuvant chemotherapy (24.9%) versus 37.0% in the monarchE Cohort 1, respectively
  - However, as data were not available for 31.4% of all pts with hRisk disease, direct comparison may not be safe
- Real-world data from the major cancer centre in South East Scotland show that node-positive HR+, HER2− EBC with high risk factors similar to the Cohort 1 of the monarchE trial is associated with poor long-term outcomes, with a clear unmet need for improved treatments
  - 2-year IDFS (92%) of hRisk pts in our study was similar to the results of the US population study on pts with HR+, HER2− EBC and ≥4 pALNs or 1−3 pALNs with additional risk factor(s) [tumor size ≥5 cm, tumour grade 3 and/or Ki-67≥ 20%] (2-year IDFS 88.1%)[3]
- Increasing burden of nodal disease was associated with worse 10-year IDFS and OS
  - 36% of pts with 1-3 pALNs plus additional risk features (tumour grade 3 and/or tumour size ≥5cm) experienced a recurrence event at 10 years; this increased to 42% for 4-9 pALNs and 52% for 10+ pALNs
- 10-year IDFS and OS were adversely affected by postmenopausal status, age ≥70 years and greater tumour size, as well
- All hRisk pts had poor long term outcomes (10-year IDFS and OS) irrespective of tumour grade
- Further analyses are planned to examine adjustment for potential drivers of OS and IDFS, which may have affected results presented in this poster

**References:**

1. Pan et al. N Engl J Med. 2017;377(19):1836–46.
2. Johnston et al. J Clin Oncol. 2020;38(34):3987–98.
3. Sheffield et al. J Clin Oncol. 2021;39(15_suppl):e18581-e.
4. Dannehl et al. J Pers Med. 2022;12(3):382.
5. Toi et al. The Oncologist. 2023;28:e77–e81

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- This work was sponsored by Eli Lilly and Company

**Disclosures:**

- RJ, WB, MR are full-time employees and minor shareholders of Eli Lilly and Company
- GT, MV, PH: University of Edinburgh, Edinburgh, UK

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St. Gallen International Breast Cancer Conference; Vienna, Austria; March 15 – 18, 2023

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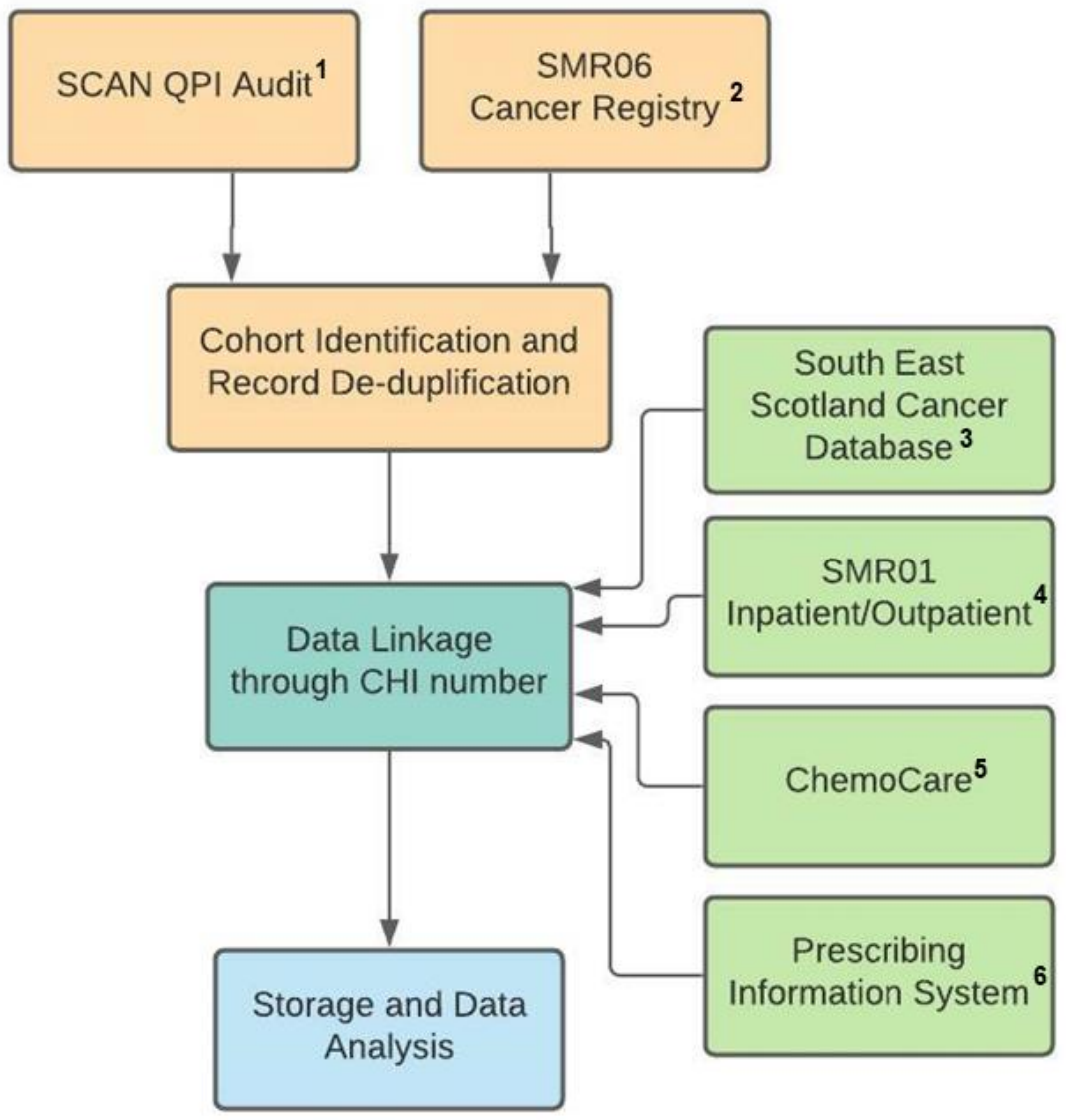


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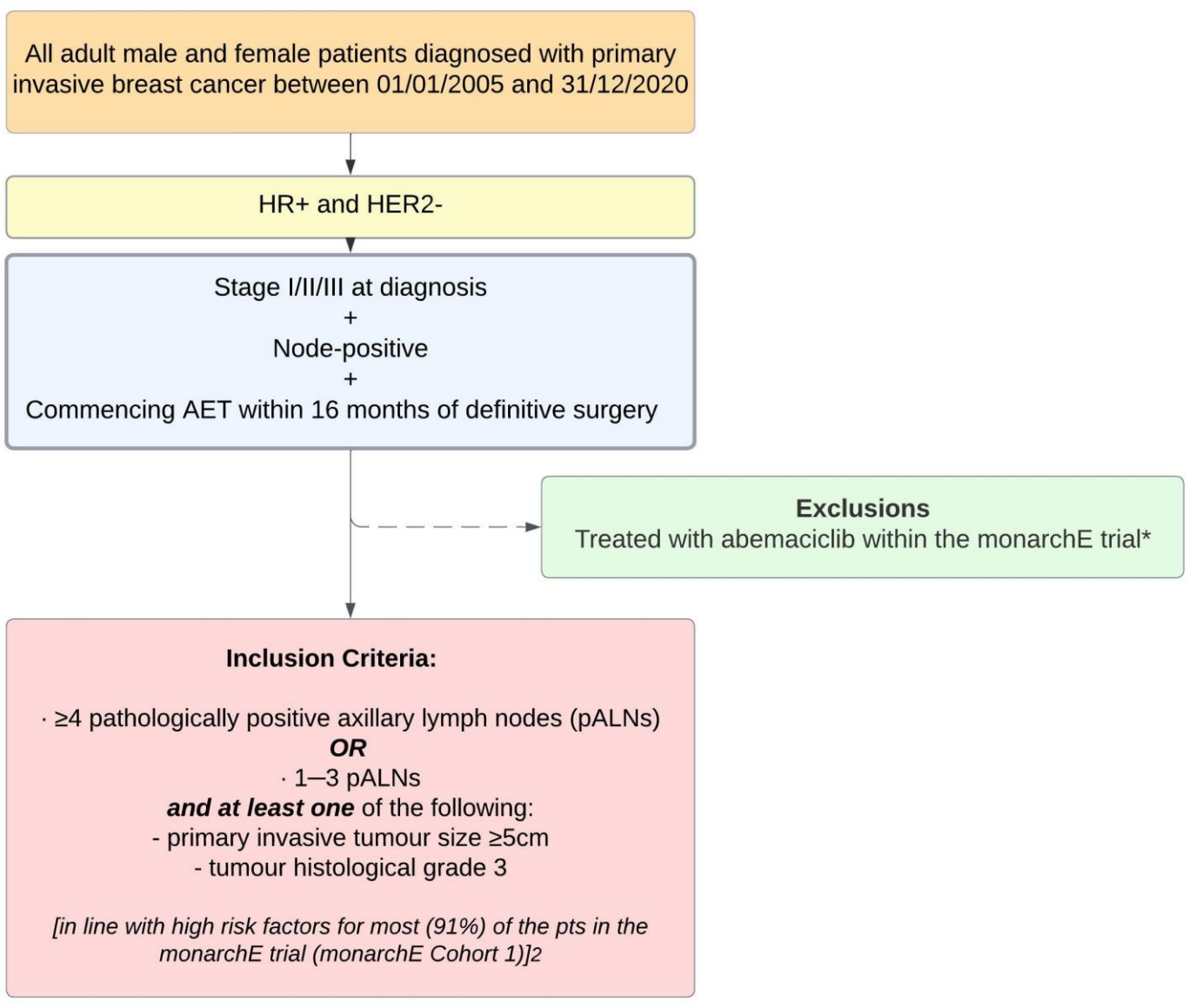


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## Treatment

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| **Anastrozole** | 99 | 6.6 |
| **Exemestane** | <10 | <0.7 |
| **Letrozole** | 516 | 34.4 |
| **Tamoxifen** | 273 | 18.2 |
| **Unspecified** | >600 | >40 |
| **Ovarian Function Suppression (n: 1498)** | | |
| **Goserelin** | 124 | 8.3 |
| **NA** | 1374 | 91.7 |
| **Radiotherapy (n: 1498)** | | |
| **Received** | 1380 | 92.1 |
| **NA** | 118 | 7.9 |

>, < when absolute count was not possible; Censoring for purposes of disclosure control was undertaken as per NHS Lothian disclosure control policy, including the suppression of numbers less than 10
NA: not available

- Mean time from diagnosis to surgery and radiotherapy was 87.7 and 215 days, respectively
- 196/1498, 13.1% of pts with hRisk disease experienced a recurrence
- Median time from diagnosis to cancer recurrence was 33.9 months (SD 29.8 months)

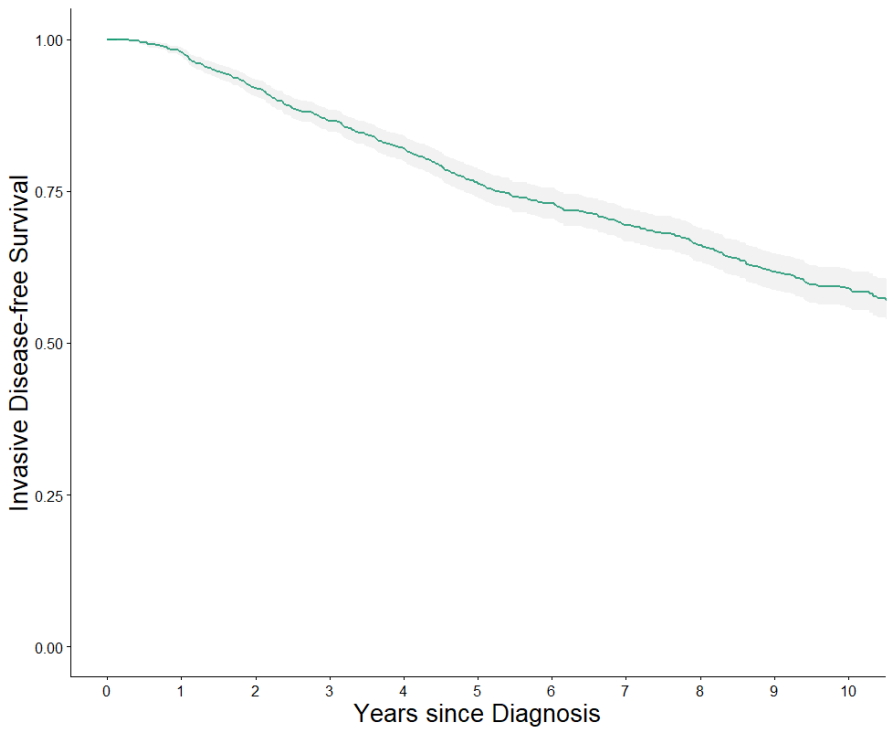
## Time from diagnosis to different treatment modalities

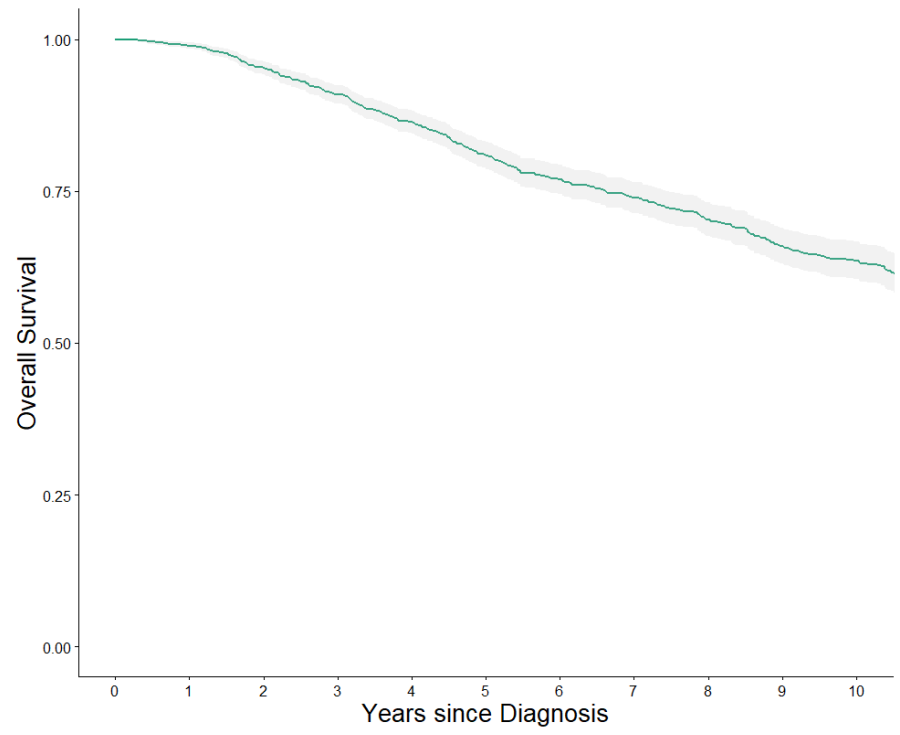
| Cohorts | | hRisk (n=1498) | |
|---|---|---|---|
| | | **Mean** | **SD** |
| **Time from Diagnosis to First Chemotherapy (n: 1027)** | | | |
| | **Time (days)** | 80.9 | 64.2 |
| **Time from Diagnosis to Surgery (n: 1498)** | | | |
| | **Time (days)** | 87.7 | 171.9 |
| **Time from Diagnosis to Radiotherapy (n: 1380)** | | | |
| | **Time (days)** | 215.0 | 89.9 |

SD: Standard Deviation

# RESULTS

## IDFS* and OS



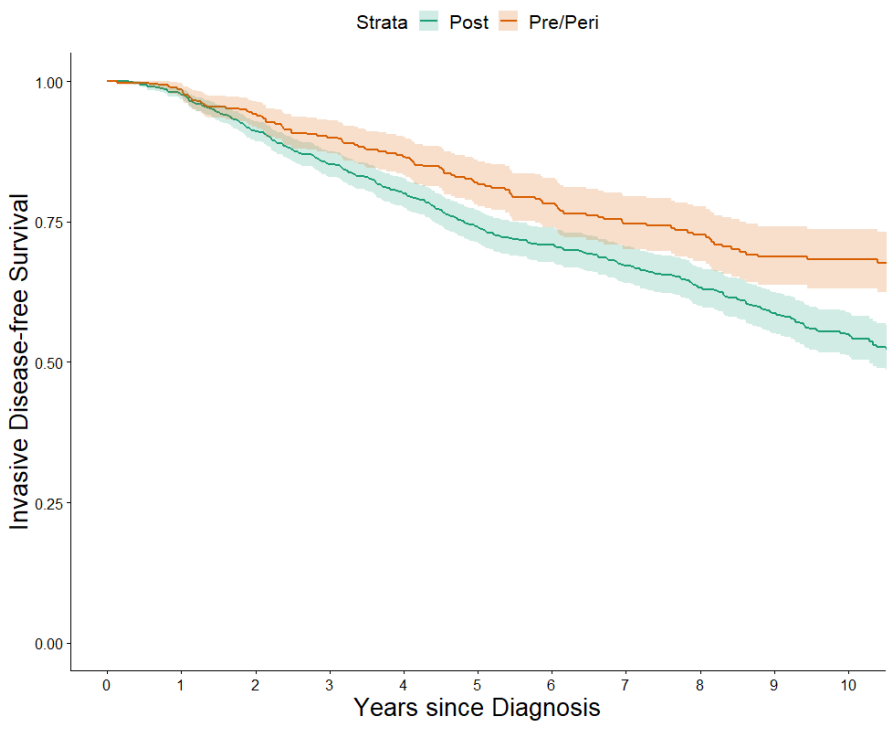



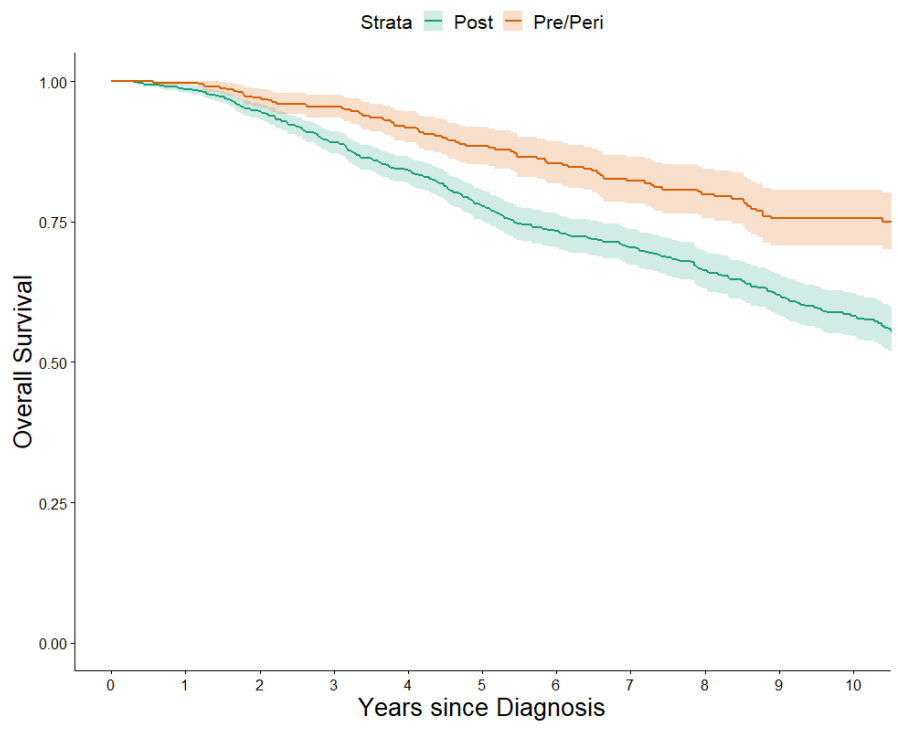

## IDFS* and OS (hRisk)

| | hRisk (n=1498) |
|---|---|
| **IDFS %** | |
| 2-year | 92 |
| 5-year | 76 |
| 10-year | 59 |
| **OS %** | |
| 2-year | 95 |
| 5-year | 81 |
| 10-year | 63 |

*IDFS was defined as per STEEP 2007 criteria

## IDFS and OS by menopausal status



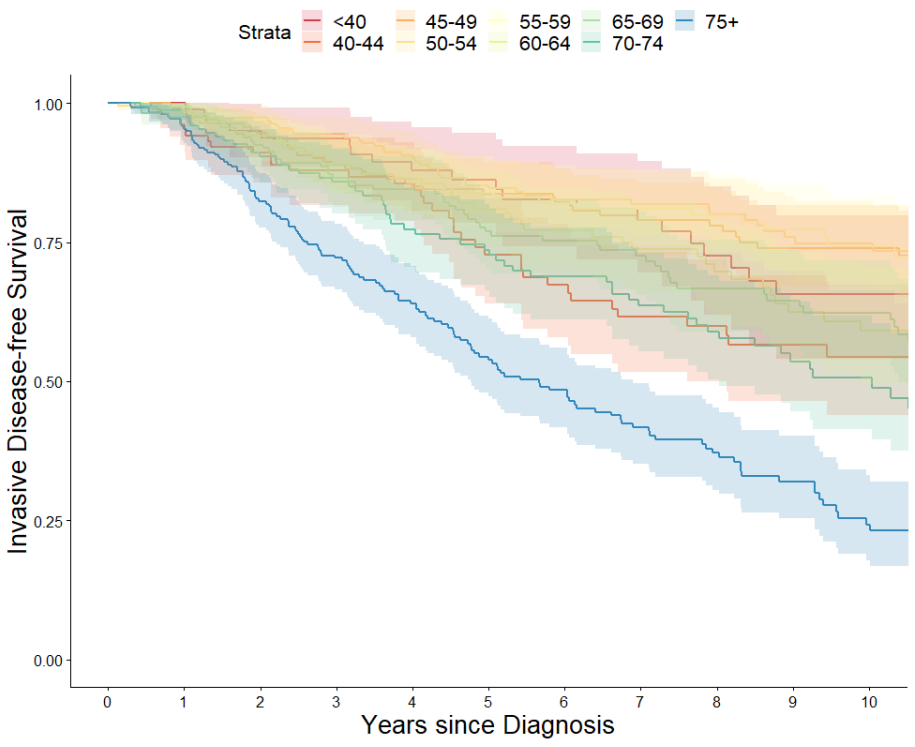

## 10-year IDFS and OS by menopausal status

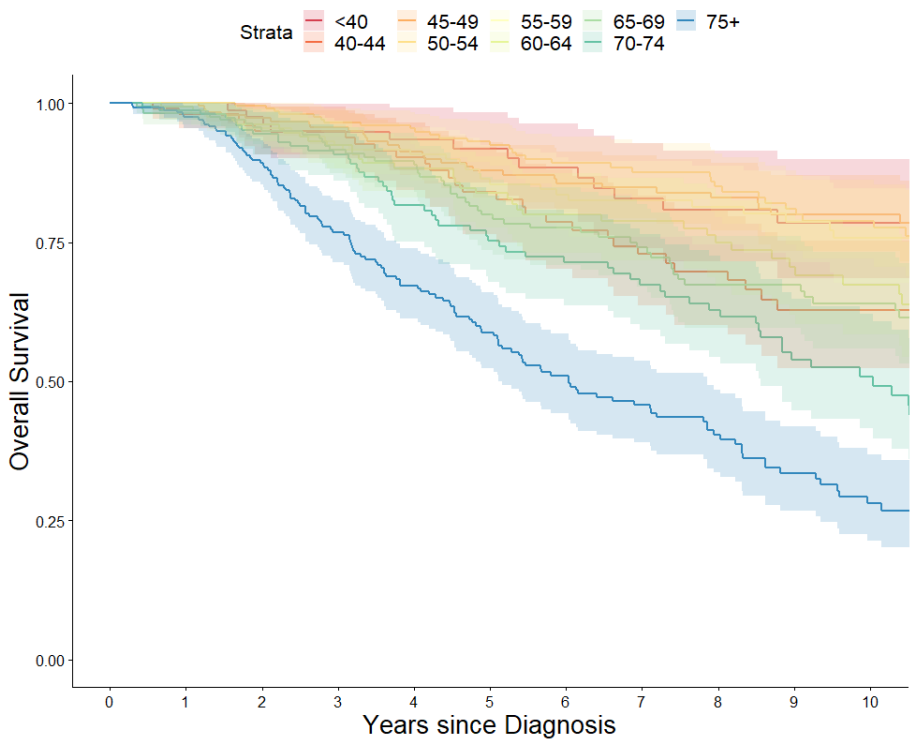
| | hRisk (n=1498) | |
|---|---|---|
| **Menopausal status** | **10-year IDFS %** | **10-year OS %** |
| **Pre/Peri** (n=427) | 68 | 76 |
| **Post** (n=1071) | 55 | 58 |

- 10-year IDFS and OS were adversely affected by postmenopausal status

# RESULTS

## IDFS and OS by age group



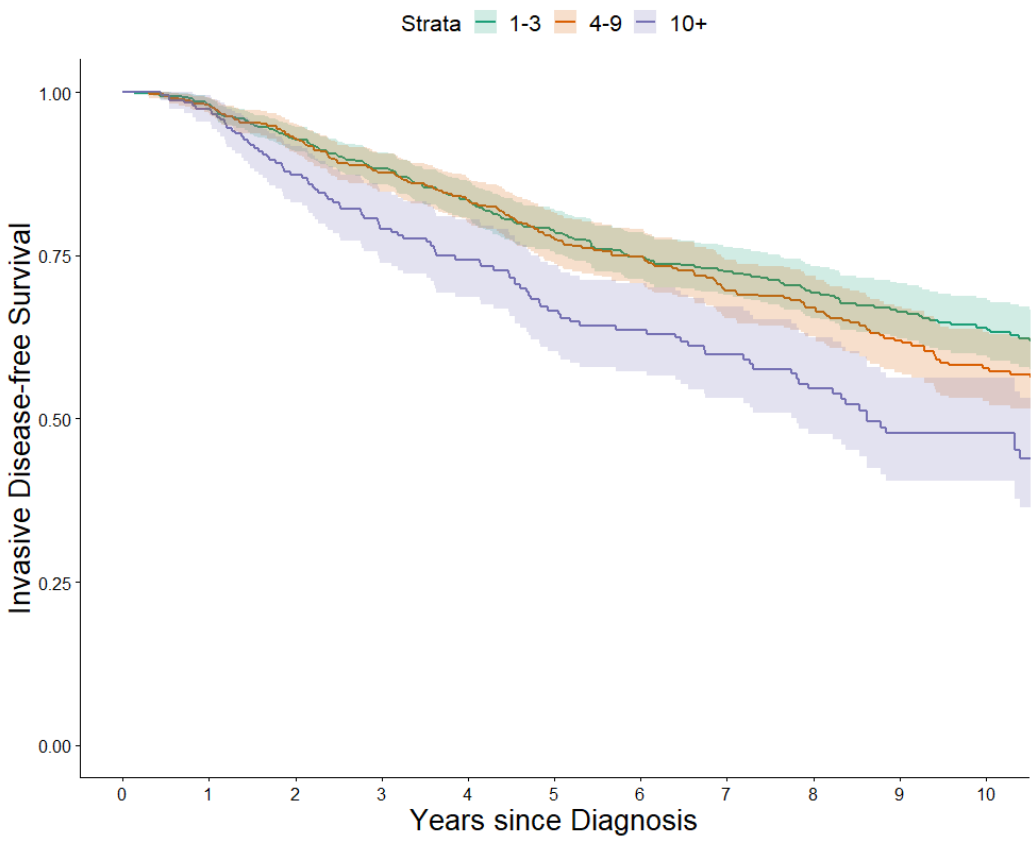

## 10-year IDFS and OS by age group

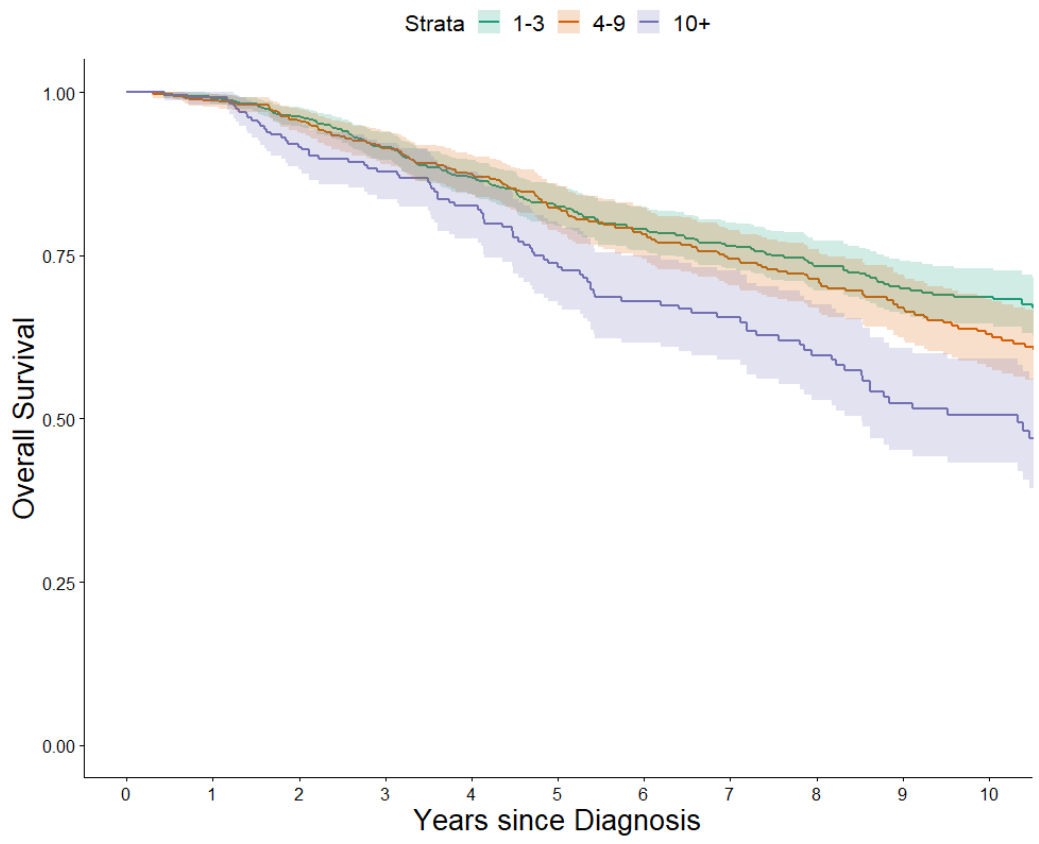
| | hRisk (n=1498) | |
|---|---|---|
| **Age group (years)** | **10-year IDFS %** | **10-year OS %** |
| <40 (n=84) | 66 | 78 |
| 40-44 (n=103) | 54 | 63 |
| 45-49 (n=192) | 74 | 80 |
| 50-54 (n=234) | 75 | 79 |
| 55-59 (n=161) | 74 | 76 |
| 60-64 (n=160) | 59 | 67 |
| 65-69 (n=165) | 62 | 64 |
| 70-74 (n=156) | 51 | 51 |
| ≥75 (n=243) | 24 | 28 |

- 10-year IDFS and OS were adversely affected by age ≥70 years

# RESULTS

## IDFS and OS by number of pALNs




## 10-year IDFS and OS by number of pALNs

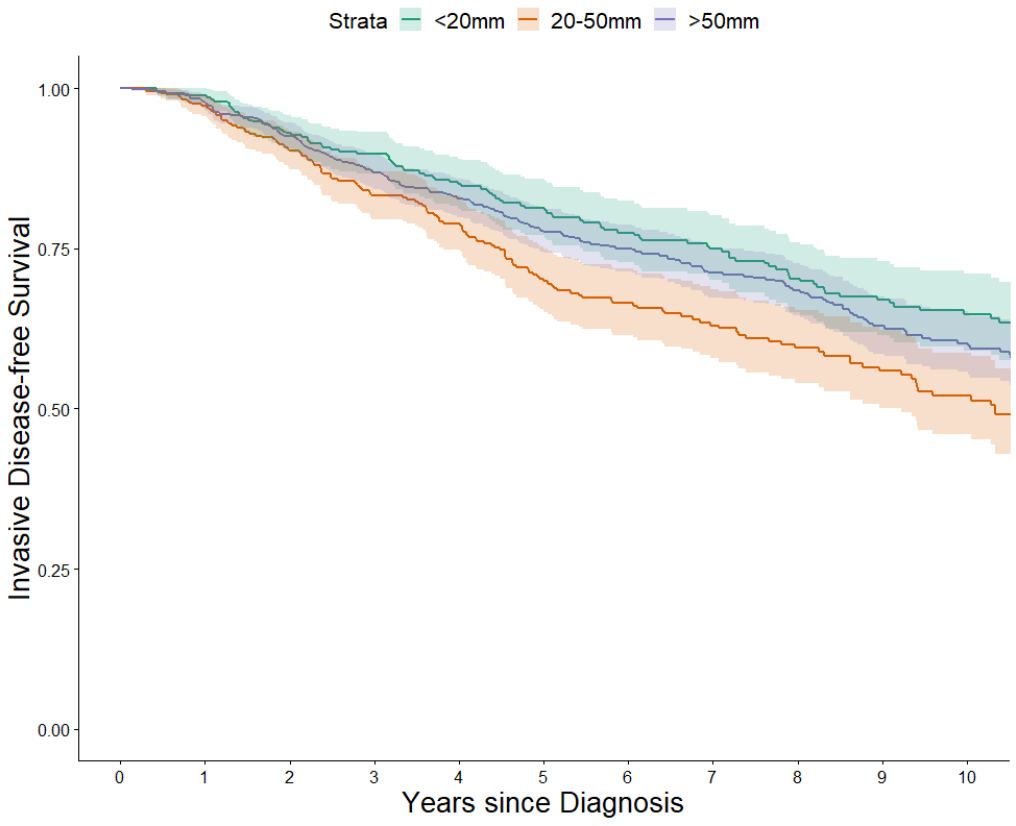
| | hRisk (n=1498) | |
|---|---|---|
| **Number of pALNs** | **10-year IDFS %** | **10-year OS %** |
| **0* (n: 0)** | N/A | N/A |
| **1-3 (n: 721)** | 64 | 69 |
| **4-9 (n: 535)** | 58 | 63 |
| **10+ (n: 242)** | 48 | 51 |

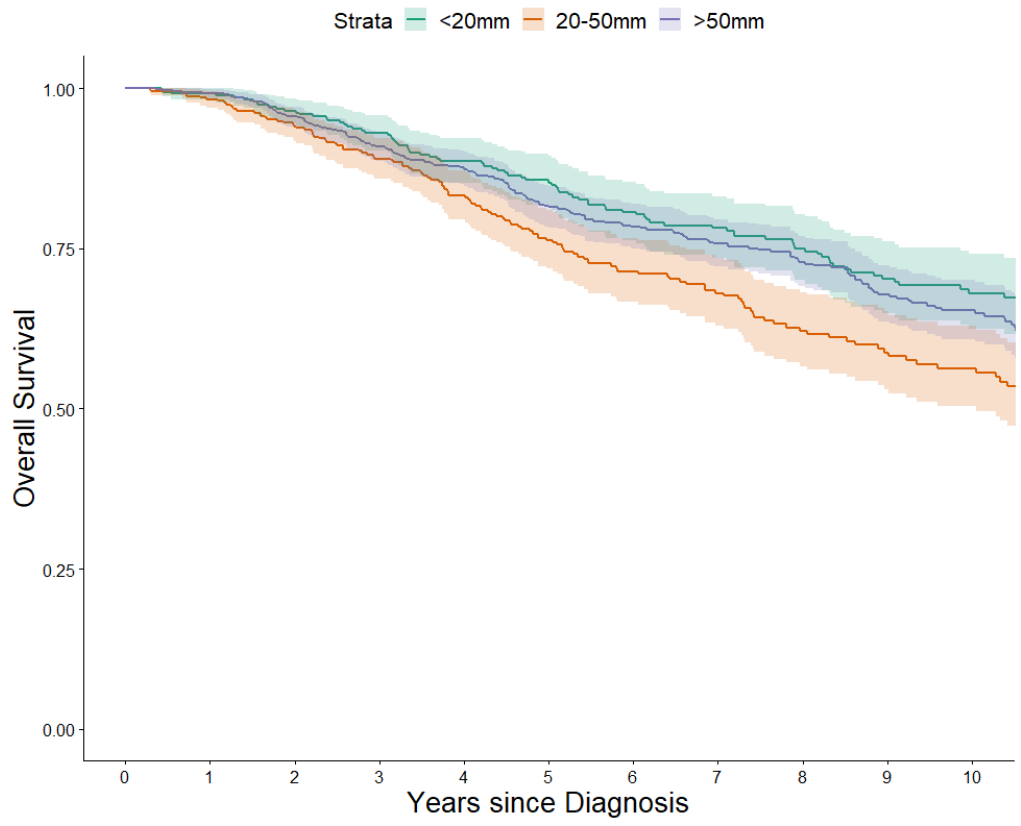
* 0 refers to clinically negative (node pathological positivity was required by protocol)

- Both 10-year IDFS and OS were adversely affected by increasing burden of nodal disease

# RESULTS

## IDFS and OS by tumour size



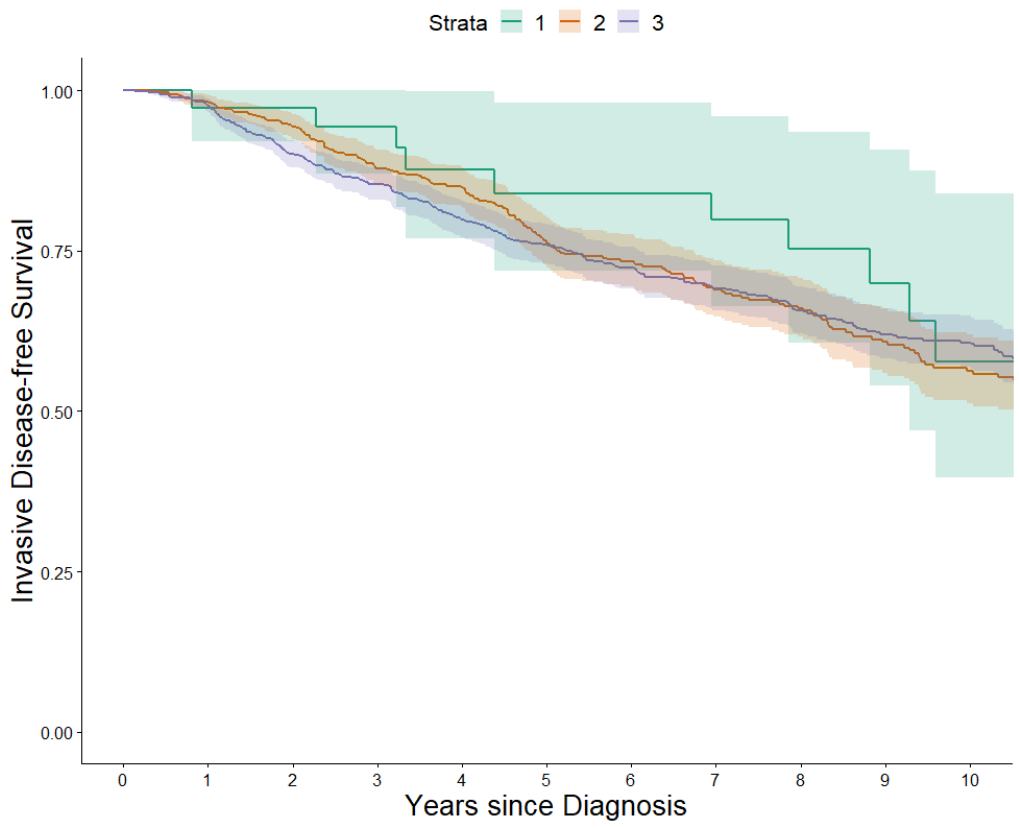



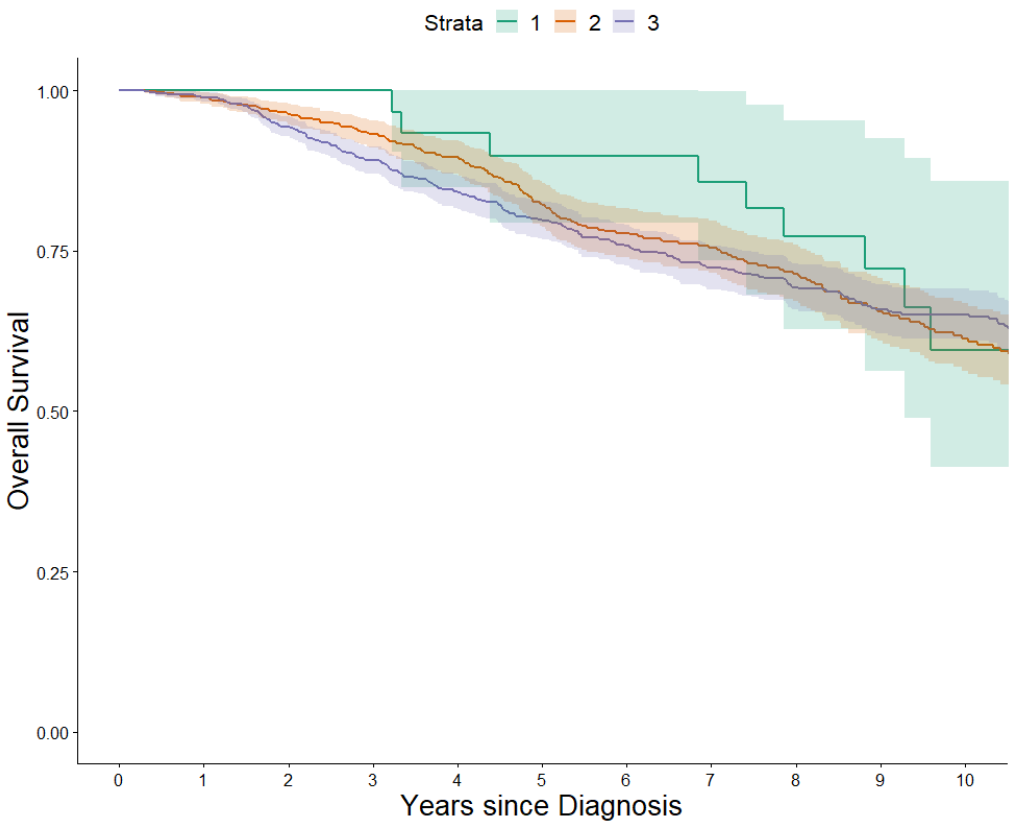

## 10-year IDFS and OS by tumour size

| | hRisk (n=1498) | |
|---|---|---|
| **Tumour size (mm)** | **10-year IDFS %** | **10-year OS %** |
| **<20 (n: 351)** | 65 | 68 |
| **20-50 (n: 702)** | 60 | 65 |
| **>50 (n: 405)** | 52 | 56 |

- Both 10-year IDFS and OS were adversely affected by increasing tumour size

## IDFS and OS by tumour grade




## 10-year IDFS and OS by tumour grade

| | hRisk (n=1498) | |
|---|---|---|
| **Tumour grade** | **10-year IDFS %** | **10-year OS %** |
| **Grade 1 (n: 36)** | 58 | 60 |
| **Grade 2 (n: 592)** | 56 | 61 |
| **Grade 3 (n: 860)** | 61 | 65 |

- Increasing tumour grade was not associated with worse survival outcomes

# RESULTS

## Health care resource utilisation

- Overall, mean number of inpatient admissions and outpatient visits in the first 2 years following diagnosis were 2.3 (SD 2.17) and 7.1 (SD 7.20), respectively
- For inpatient admissions, mean cumulative length of stay (per patient) and average length of stay (per admission per patient) in the first 2 years following diagnosis was 10.8 (SD 18.34) and 4.9 (SD 8.45) days, respectively

# LIMITATIONS and SUMMARY

## *LIMITATIONS*

- Additional high risk features not captured here due to study design may also have affected outcomes
- This study population represents a historical cohort (2005-2021) thus outcomes need to be interpreted with caution if drawing conclusions with current practices
- In order to minimise the effect or bias from clinical trial participants within this study, exclusion of pts from the monarchE trial was applied; the study site did not participate in other major adjuvant CDK4/6i trials
- Baseline demographic differences compared to the monarchE trial, e.g. higher median age and higher post-menopausal women representation, may be attributed to real-world population versus clinical trial selection biases
  - Indeed, the German real-world study of both node-negative and node-positive EBC reported a proportion of pts with HR+ HER2− EBC being post-menopausal which is nearly identical to our study (71.9% vs 71.5%, respectively)[4]

## *SUMMARY*

- Approximately half of pts with hRisk disease (52.1%) had ≥4 pALNs and more than a quarter (27.6%) had tumour size ≥5cm
- Nearly a quarter of pts with hRisk disease received neoadjuvant chemotherapy (24.9%) versus 37.0% in the monarchE Cohort 1, respectively
  - However, as data were not available for 31.4% of all pts with hRisk disease, direct comparison may not be safe
- Real-world data from the major cancer centre in South East Scotland show that node-positive HR+, HER2− EBC with high risk factors similar to the Cohort 1 of the monarchE trial is associated with poor long-term outcomes, with a clear unmet need for improved treatments
  - 2-year IDFS (92%) of hRisk pts in our study was similar to the results of the US population study on pts with HR+, HER2− EBC and ≥4 pALNs or 1−3 pALNs with additional risk factor(s) [tumor size ≥5 cm, tumour grade 3 and/or Ki-67≥ 20%] (2-year IDFS 88.1%)[3]
- Increasing burden of nodal disease was associated with worse 10-year IDFS and OS
  - 36% of pts with 1-3 pALNs plus additional risk features (tumour grade 3 and/or tumour size ≥5cm) experienced a recurrence event at 10 years; this increased to 42% for 4-9 pALNs and 52% for 10+ pALNs
- 10-year IDFS and OS were adversely affected by postmenopausal status, age ≥70 years and greater tumour size, as well
- All hRisk pts had poor long term outcomes (10-year IDFS and OS) irrespective of tumour grade
- Further analyses are planned to examine adjustment for potential drivers of OS and IDFS, which may have affected results presented in this poster

# REFERENCES, ACKNOWLEDGEMENTS, DISCLOSURES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