EndoPredict®

Breast Cancer Prognostic Test

Long-term prospective data for informed and trustful decisions

Results from The Technical University of Munich's prospective registry

Risk stratification and chemotherapy benefit prediction in ER-positive, HER2-negative early breast cancers

Myriad genetics

5-year prospective data in a real-world patient cohort

Study population

- 368 HR+, HER2-, N0-3
- Patients prospectively enrolled in a clinical routine setting 2012 – 2015
- Demographic, clinical and pathological data assessed at baseline
- All tumour samples tested with EndoPredict

Analysis

- Treatment compliance, local recurrence, distant metastases and survival were evaluated
- Statistical analysis by Kaplan-Meier and Cox proportional hazards regression model

Patient characteristics

- Median age 60
- 33% pre-menopausal
- 35% pT2, 3% pT3
- 65% Grade 2, 16% Grade 3
- 24% 1-3 positive lymph nodes
- 65% EPclin low-risk

Significantly prognostic in a prospective real-world patient cohort

Classification by EPclin Risk Score

EPclin high-risk
35%
(n=130)

EPclin low-risk
65%
(n=238)

DMFS by EPclin Risk Class

- Median follow-up 8.2 years
- 5-year DMFS:
  - **EPclin low 96.6%**
  - **EPclin high 85.5%**
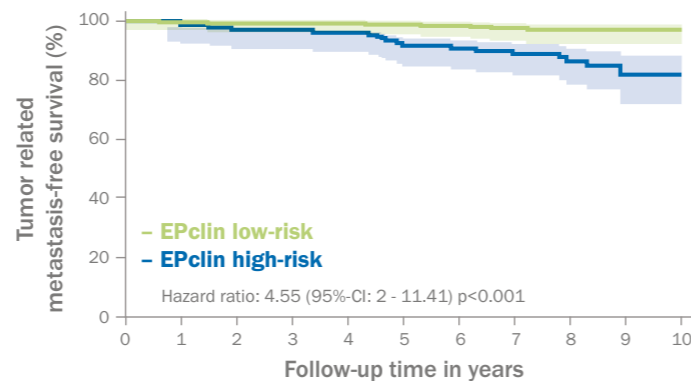 - HR 2.21, p=0.005

EndoPredict is significantly prognostic with excellent 5y outcome of EPclin low-risk patients in this prospective real-world patient cohort

Excellent 5-year outcome of EPclin low-risk patients

DFS by EPclin Risk Class

– EPclin low-risk
– EPclin high-risk
Hazard ratio: 2.08 (95%-CI: 1.26 - 3.44) p=0.004
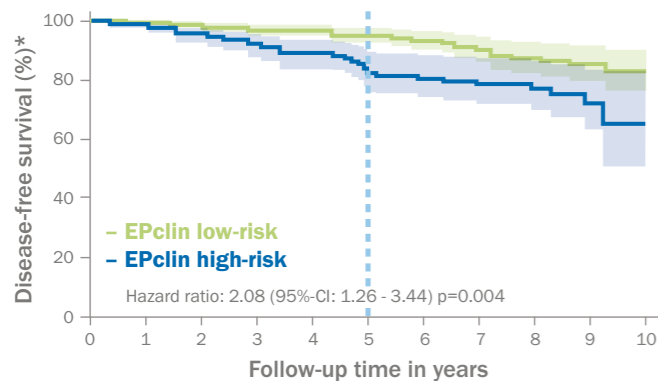
Tumor related DMFS by EPclin Risk Class

– EPclin low-risk
– EPclin high-risk
Hazard ratio: 4.55 (95%-CI: 2 - 11.41) p<0.001

Numbers at risk

Low	238	234	231	223	217	214	209	187	110	51	6
High	130	126	123	116	109	99	95	85	63	22	2

Numbers at risk

Low	238	234	231	224	220	217	213	190	113	51	6
High	130	127	124	119	112	103	99	89	66	22	3

*Including death by any cause

Prospective confirmation of chemotherapy benefit prediction

DFS in EPclin high risk patients by CTx treatment

– EPclin high with CTx
– EPclin high no CTx
Hazard ratio: 0.46 (95%-CI: 0.23 - 0.95) p=0.036
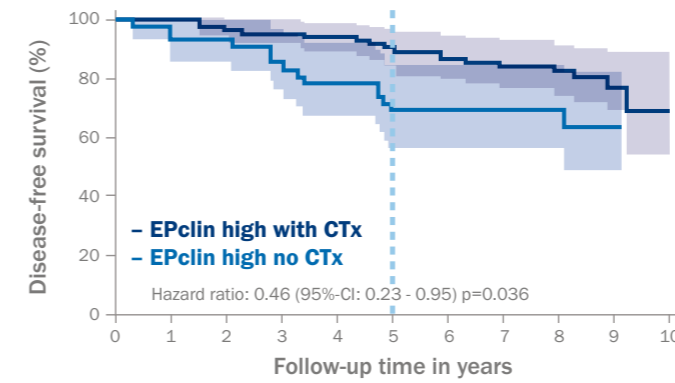
Numbers at risk

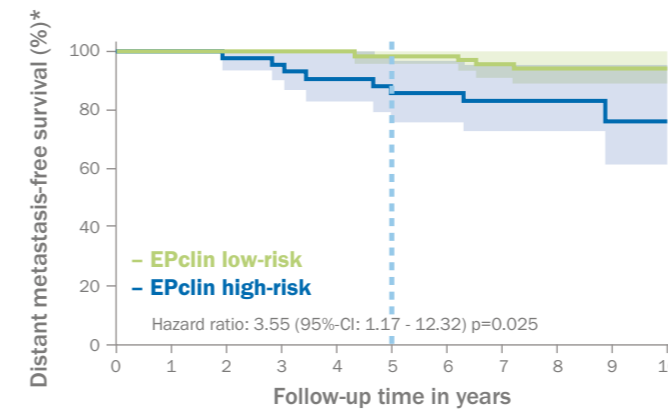|										
EPclin high with CTx	87	86	83	80	76	71	68	63	49	19	2
EPclin high no CTx	43	40	40	36	33	28	27	22	14	3

EndoPredict predicts chemotherapy benefit

- 130 pts (35%) classified as EPclin high-risk
- 67% received chemotherapy
- 5-year DFS
  - **EPclin high with CTx 89.1%** (95% CI: 0.827-0.961)
  - **EPclin high no CTx 68.9%** (95% CI: 0.562-0.845)
  - HR 0.46, p=0.036

Patients categorized as EPclin high-risk significantly benefitted from adjuvant chemotherapy

Prospective confirmation of pre- and postmenopausal validation studies
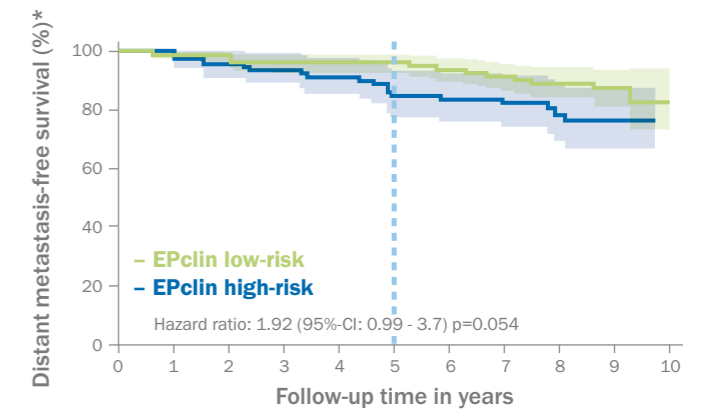
Premenopausal patients

– EPclin low-risk
– EPclin high-risk
Hazard ratio: 3.55 (95%-CI: 1.17 - 12.32) p=0.025

Postmenopausal patients

– EPclin low-risk
– EPclin high-risk
Hazard ratio: 1.92 (95%-CI: 0.99 - 3.7) p=0.054

Numbers at risk

Low	77	76	76	73	73	70	70	63	40	20	2
High	45	45	44	42	38	35	34	29	25	10	3

Numbers at risk

Low	157	154	151	147	143	143	139	123	73	31	4
High	83	80	78	75	72	66	63	58	40	12

*Including death by any cause

EndoPredict accurately identifies patients who may safely avoid chemotherapy, regardless of menopausal status

Prospective confirmation of superiority compared to Ki67 classification

Classification of Ki67 low/high by EPclin

19.2% Discordant

33.3%

% of patients

100 90 80 70 60 50 40 30 20 10 0

Ki67 low (0-10%) Ki67 high (25-100%)

■ EPclin low
■ EPclin high
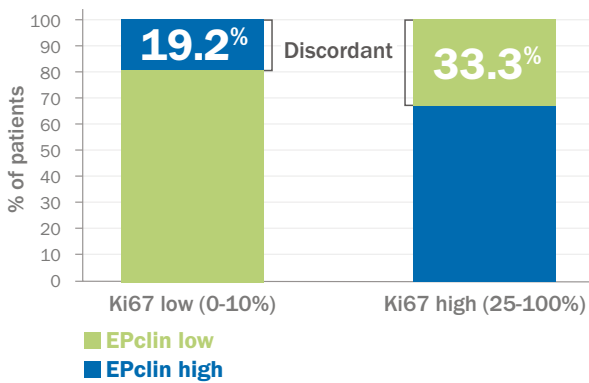
Discordant classification

- 19% of luminal A (Ki67 low) classified as EPclin high
- 33% of luminal B (Ki67 high) classified as EPclin low

  EPclin-based risk stratification was significantly associated with improved DFS of EPclin low-risk patients compared to EPclin high-risk patients in both Ki67 subtypes

- Ki67 high: HR 3.77 (95% CI 1.19-18.93; p=0.022)
- Ki67 low: HR 4 (95% CI 1.25- 12.04; p=0.021)

EndoPredict showed better classification accuracy in comparison to Ki67 subtypes, resulting in a more precise estimation of prognosis

Long-term prognostic in prospective real-world patient cohort

Excellent 5y outcome of EPclin low-risk patients

Prospective confirmation of chemotherapy benefit prediction

Patients categorized as EPclin high-risk significantly benefitted from adjuvant chemotherapy

Prospective confirmation of pre- and postmenopausal validation studies

Accurately identifies patients who may safely avoid chemotherapy, regardless of menopausal status

Prospective confirmation of improved classification over conventional factors

Better classification accuracy in comparison to Ki67 subtypes

References:
Klein, Evelyn et al. "Long-term outcome data using EndoPredict as risk stratification and chemotherapy decision biomarker in hormone receptor positive, HER2-negative early breast cancer." SABCS 2022.

The prospective registry at the Technical University of Munich in Germany provides the first prospective outcome results for patients whose adjuvant systemic therapy recommendation was based on the EndoPredict test result. Previously published in Archives of Gynecology and Obstetrics 2020, this update reports longer-term outcomes with a median follow-up of 8.2 years.

Myriad
genetics