Survivorship Update SABCS 2022

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Disclosures/Conflicts of Interest

- None

SABCS 2024 Highlights

- GS4-09 Pregnancy Outcome and Safety of Interrupting Therapy for women with Endocrine Responsive Breast Cancer: Primary Results from the POSITIVE trial Partridge et al.
- PD 6 01 Association between the CARG-BC Score and Clinical Decline After Adjuvant Chemotherapy in Fit Older Adults with Breast Cancer: Results from Hurria Older PatiEnts (HOPE) Ji et al.
- PD 8 06 Incidence of Acute and Persistent Clinically Meaningful Chemotherapy Induced Peripheral Neuropathy in Patients with Early-Stage Breast Cancer Receiving Taxane Therapy: SWOG S1714 Trivedi et al.
- PD 8 04 The Role of Yoga as a Complementary Therapy in women undergoing treatment for breast cancer: A randomized, controlled trial. Nair et al.
- PD 8 05 Effectiveness of Electroacupuncture versus Auricular Acupuncture in Reducing Pain and Improving Quality of Life in Breast Cancer Survivors with Chronic Musculoskeletal Pain Bao et al.

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ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Pregnancy Outcome and Safety of Interrupting Therapy for women with endocrine responsIVE breast cancer

Initial Results from the **POSITIVE Trial**
(IBCSG 48-14 / BIG 8-13 / Alliance A221405)

Ann Partridge on behalf of the POSITIVE Consortium

A H Partridge, S M Niman, M Ruggeri, F A Peccatori, H A Azim Jr, M Colleoni, C Saura, C Shimizu, A Barbro Sætersdal, J R Kroep, A Mailliez, E Warner, V F Borges, F Amant, A Gombos, A Kataoka, C Rousset-Jablonski, S Borstnar, J Takei, J Eon Lee, J M Walshe, M Ruíz Borrego, H CF Moore, C Saunders, V Bjelic-Radisic, S Susnjar, F Cardoso, K L Smith, T Ferreiro, K Ribi, K J Ruddy, S El-Abed, M Piccart, L A Korde, A Goldhirsch†, R D Gelber, O Pagani

BACKGROUND

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- Many young breast cancer (BC) survivors desire pregnancy[1,2]
- Retrospective evidence shows pregnancy after BC does not worsen disease outcomes, regardless of hormone receptor (HR) status[3]
- Standard 5-10 years of adjuvant endocrine therapy (ET) compromises conception in women with (HR+) disease[4]
- **Pregnancy after BC and interruption of ET to attempt pregnancy have not been studied prospectively**

1 Ruddy KJ et al. J Clin Oncol 2014;32(11):1151-6. DOI: 10.1200/JCO.2013.52.8877
2 Ruggeri M et al. Breast 2019;47:85-92. DOI: 10.1016/j.breast.2019.07.001
3 Lambertini M et al. J Clin Oncol 2021;39(29):3293-3305. DOI: 10.1200/JCO.21.00535
4 Paluch-Shimon S et al. Ann Oncol. 2022 Aug 4:S0923-7534(22)01858-0

POSITIVE TRIAL DESIGN

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- Prospective, single-arm trial to:
  - address the question: is it safe, from a BC relapse perspective, to temporarily interrupt ET to attempt pregnancy?
  - enroll only women with HR+ disease
- Study designed with specific safety criteria:
  - duration of prior endocrine therapy
  - timing of pregnancy attempt and resumption of ET

ELIGIBILITY

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- Premenopausal women wishing to become pregnant
- Age ≤42 years at study entry
- At least 18 months and no more than 30 months of prior adjuvant ET for stage I-III HR+ BC
  - Prior neo/adjuvant chemotherapy ± fertility preservation allowed
- No clinical evidence of recurrence

TRIAL PROCEDURES

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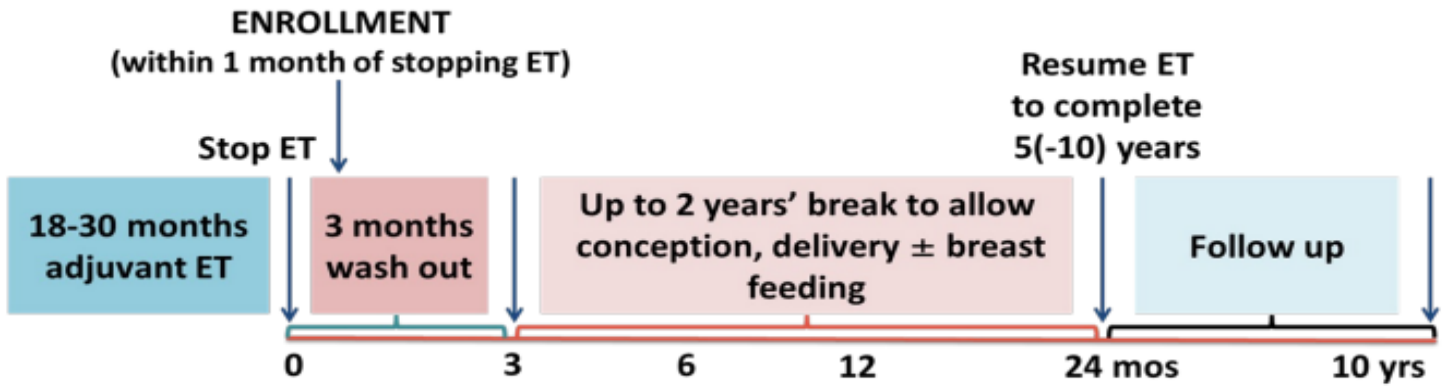
- Planned ET interruption (within 1 month of trial enrollment):
- Up to 2 years to attempt pregnancy, conceive, deliver, and breastfeed, including 3-months washout period
  - If no pregnancy by 1 year, fertility assessment strongly recommended
- ET resumption strongly recommended after pregnancy to complete planned 5-10 yrs
- Long-term follow-up



ENDPOINTS

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- **Primary**
  - **Breast cancer-free interval (BCFI)** = time from enrollment (after 18-30 months of ET) to the first ipsilateral / locoregional / contralateral invasive disease or distant recurrence
- **Secondary**
  - Pregnancy outcomes
  - Offspring outcomes
  - Breastfeeding
  - Use of assisted reproductive technology (ART)
  - Adherence to endocrine treatment
  - Distant recurrence-free interval (DRFI) = time from enrollment to the first BC distant recurrence

STATISTICAL CONSIDERATIONS

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- Planned sample size = 500 women
- Primary analysis planned after 1600 patient-years of follow-up (pyfu), with **≤46 BCFI events considered safe**

Today we present the primary analysis of breast cancer outcomes, and secondary pregnancy and offspring outcomes

- A cohort of 1499 SOFT/TEXT patients used as external control[1]
- Bootstrapped Matching Method[2] to compare POSITIVE vs. SOFT/TEXT controls for BCFI and DRFI

1 Sun Z et al. Breast 2020;53:1-7. DOI: 10.1016/j.breast.2020.05.012

2 Efron B, Tibshirani RJ. Introduction to the Bootstrap: CRC Press, 1993

TRIAL ENROLLMENT (Dec 2014 - Dec 2019)

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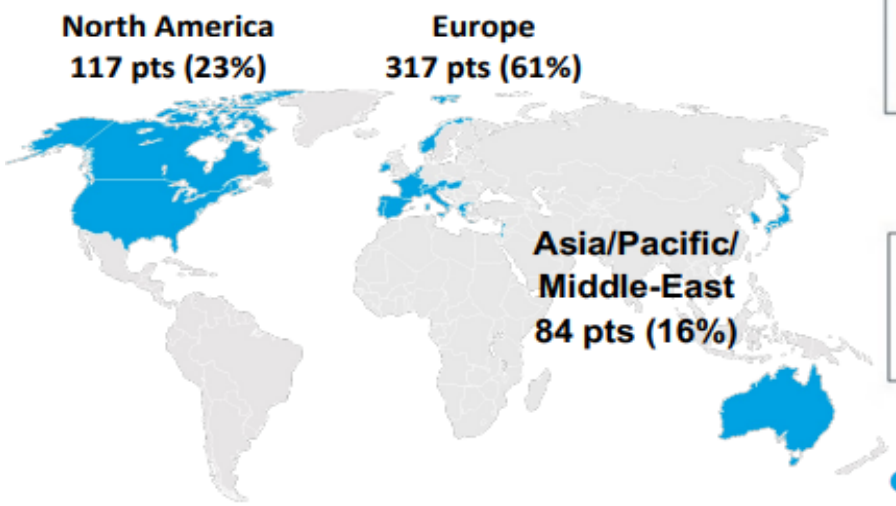
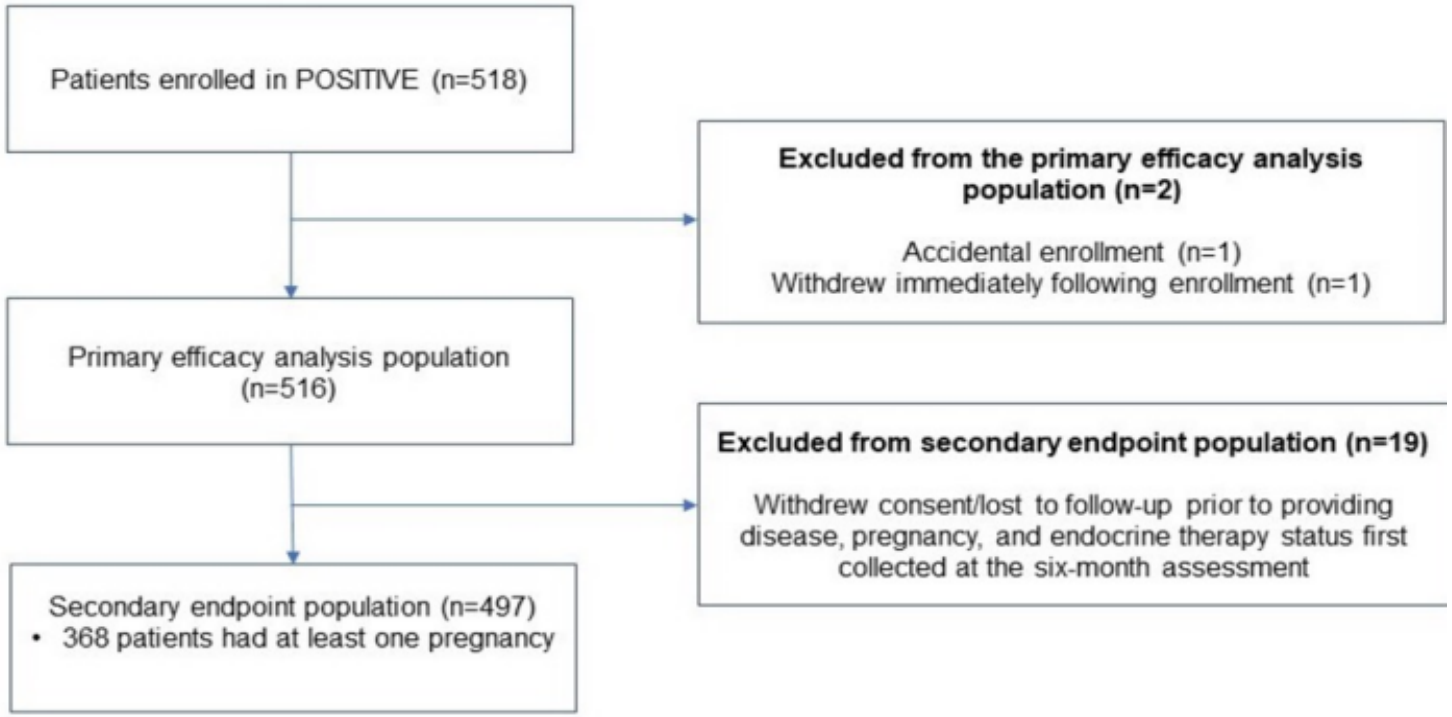
- 116 centers
- Across 20 countries
- On 4 continents





- Median time from BC diagnosis to enrollment 29 months
- Median follow-up 41 months

KEY PATIENT CHARACTERISTICS

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	N	%
	516	**100**
Age at enrollment ***Median 37 years (range 27-43 years)***		
<35	177	34%
35-39	221	**43%**
40-42	118	23%
Number of prior births		
0	387	**75%**
1	107	21%
≥ 2	22	4%
TNM stage		
I	242	**47%**
II	240	**47%**
III	31	6%
Unknown	3	1%

Partridge AH et al. Breast 2021;59:327-338.
DOI: 10.1016/j.breast.2021.07.021

TREATMENT PATTERNS

	N	%
	516	**100**
Endocrine therapy prior to enrollment ***Median duration: 23.4 months***		
SERM alone	215	**42%**
SERM+OFS	184	**36%**
AI+OFS	82	16%
Other	35	7%
Prior (neo-)adjuvant chemotherapy		
None	196	38%
Yes	320	**62%**
Breast surgery		
Mastectomy	233	45%
Breast conserving procedure	283	55%

Partridge AH et al. Breast 2021;59:327-338. DO 10.1016/j.breast.2021.07.021

BREAST CANCER OUTCOMES – POSITIVE only

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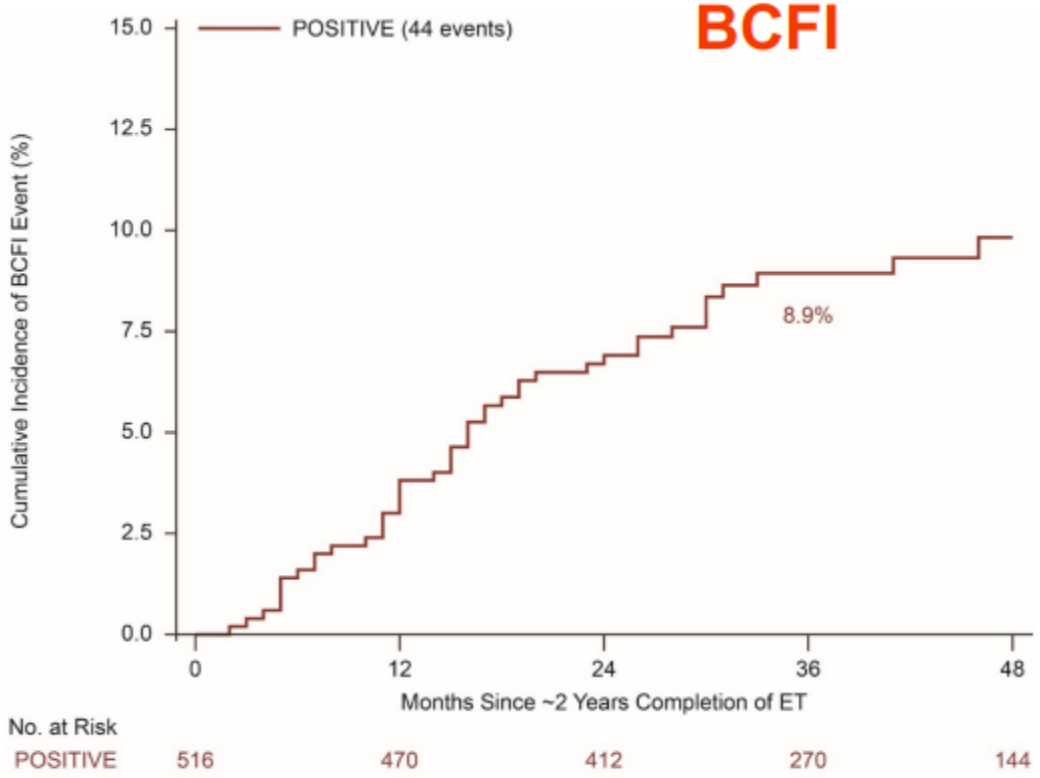
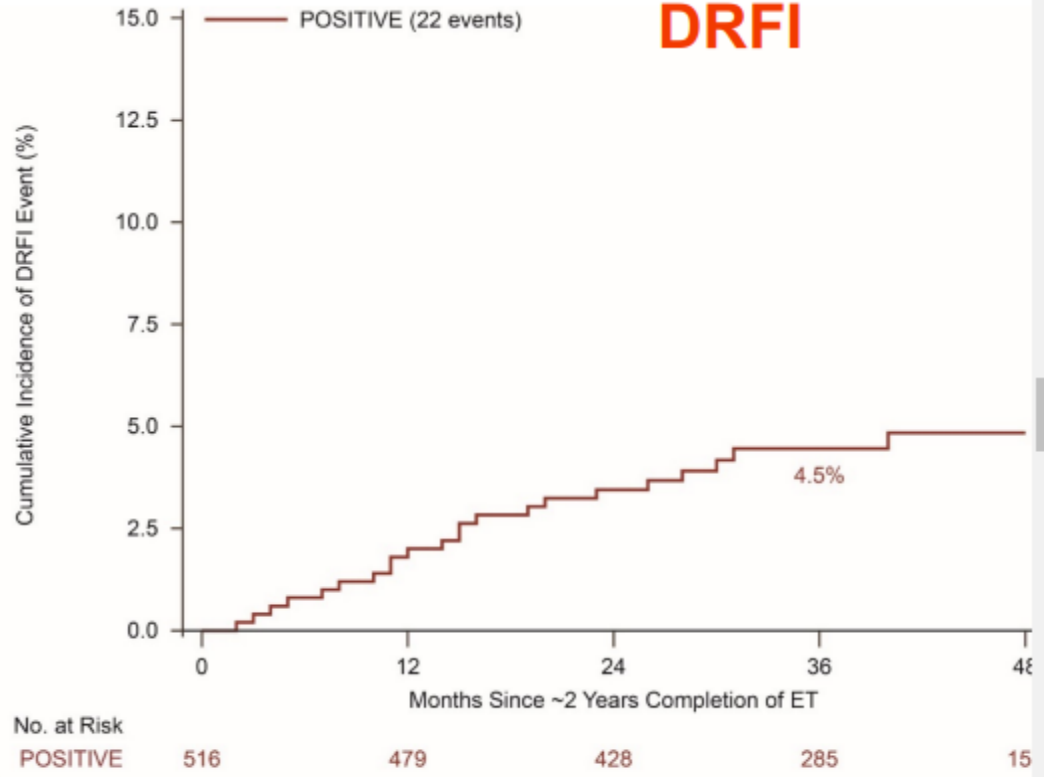
BCFI



DRFI



1638 patient-years of follow-up (41 months median follow-up)

BREAST CANCER OUTCOMES – POSITIVE & SOFT/TEXT

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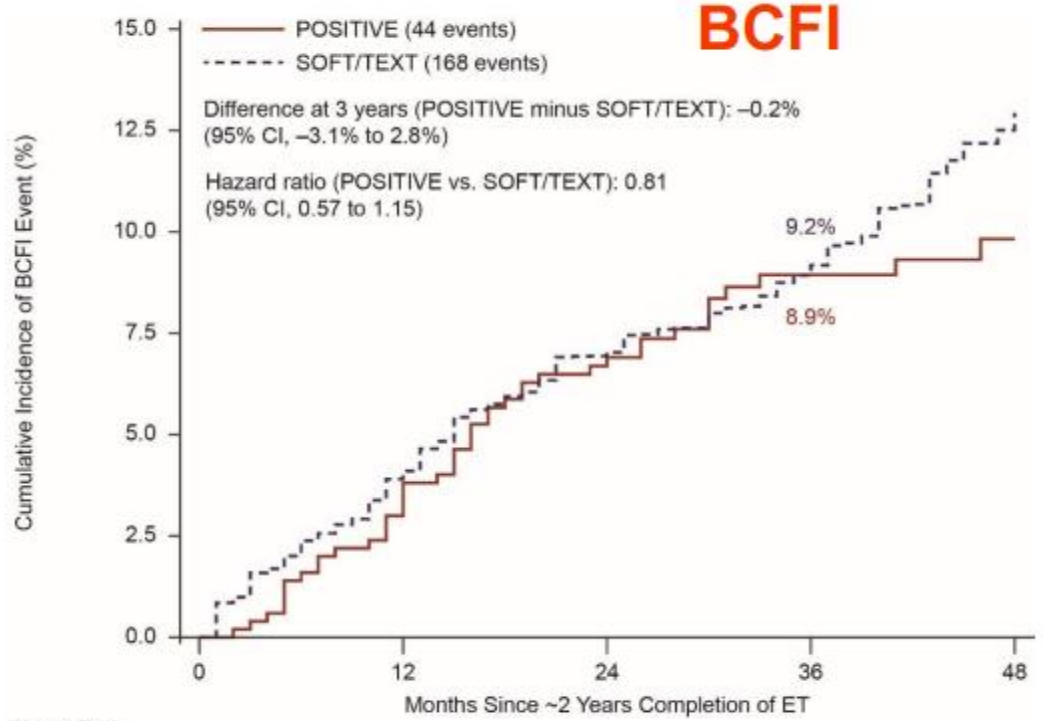
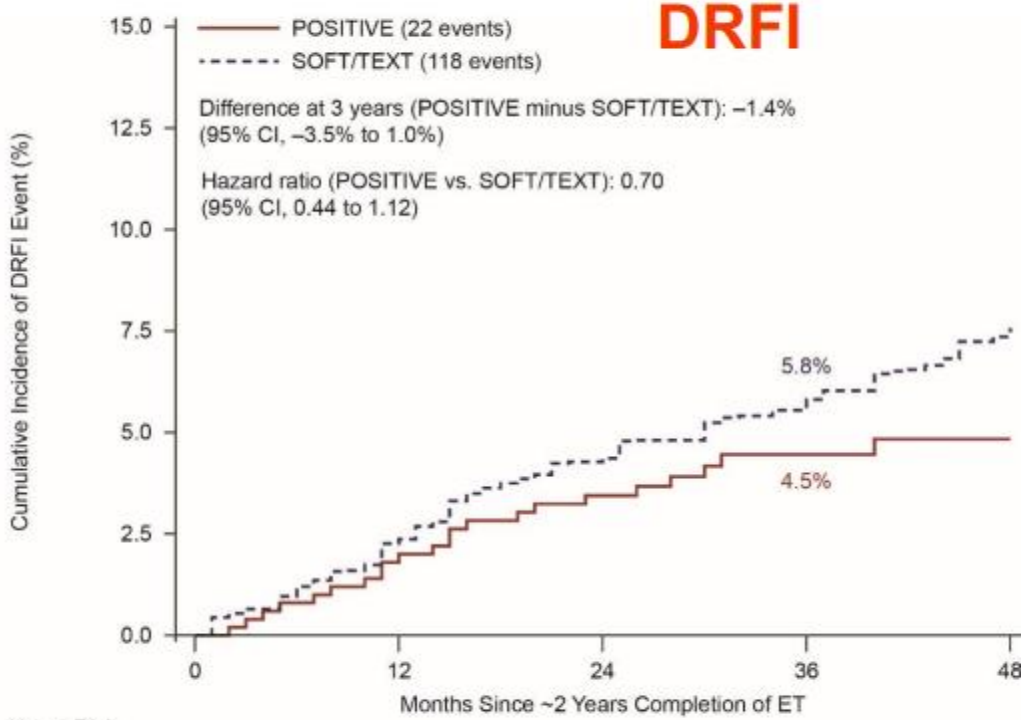
BCFI



No. at Risk					
POSITIVE	516	470	412	270	144
SOFT/TEXT	1499	1336	1159	943	646

DRFI



No. at Risk					
POSITIVE	516	479	428	285	15
SOFT/TEXT	1499	1349	1179	969	66

3-YEAR BCFI CUMULATIVE INCIDENCE – POSITIVE only

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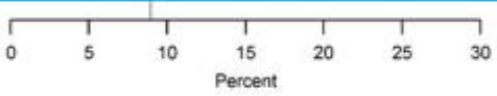
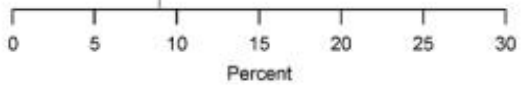
- 3-year BCFI varied according to clinical-pathological characteristics

Subgroup	No. Events / Total No. Patients	3-Year BCFI Cumulative Incidence Percent (95% CI)
Overall	44/516	8.9 (6.7–11.9)
Age at enrollment (years)		
<35	14/177	9.1 (5.4–14.9)
35–39	18/221	7.7 (4.8–12.3)
40–42	12/118	11.2 (6.5–18.9)
BMI at enrollment (kg/m²)*		
<25	34/371	9.5 (6.8–13.2)
25 to <30	7/90	8.0 (3.9–16.1)
≥30	3/49	7.2 (2.4–20.9)
BRCA status		
BRCA Positive	5/38	14.5 (6.3–31.6)
Other mutation	4/21	10.5 (2.7–35.9)
No documented mutation†	35/457	8.4 (6.1–11.5)
HER2 status		
Positive	6/134	4.9 (2.2–10.6)
Negative	38/382	10.4 (7.6–14.1)
Nodal status		
pN0	21/342	6.6 (4.3–10.0)
pN+ 1–3	18/151	12.6 (8.1–19.3)
pN+ 4–9	5/23	18.7 (7.4–42.6)



Subgroup	No. Events / Total No. Patients	3-Year BCFI Cumulative Incidence Percent (95% CI)
Tumor size (cm)‡		
≤2	24/331	7.6 (5.1–11.2)
>2 to ≤5	16/161	10.3 (6.3–16.5)
>5	4/21	21.1 (8.3–47.6)
Tumor grade‡		
1 (BRE 3–5)	5/89	6.4 (2.7–14.8)
2 (BRE 6–7)	21/252	8.9 (5.8–13.6)
3 (BRE 8–9)	18/172	10.4 (6.6–16.2)
Breast surgery		
Mastectomy	29/233	12.7 (8.9–17.9)
Breast conservation	15/283	5.7 (3.4–9.5)
Prior endocrine therapy		
SERM alone	20/215	9.9 (6.4–15.1)
SERM+OFS	20/184	11.4 (7.4–17.4)
AI+OFS	1/82	1.2 (0.2–8.4)
Other	3/35	8.8 (2.9–24.9)
Prior chemotherapy		
Anthracycline (A) based	8/36	19.4 (9.8–36.5)
Taxane (T) based	4/66	6.7 (2.5–16.9)
Both A and T based	16/215	8.4 (5.2–13.4)
Neither A or T based	0/3	
None	16/196	8.4 (5.1–13.6)



BCFI FOR PREGNANT vs NON PREGNANT PATIENTS

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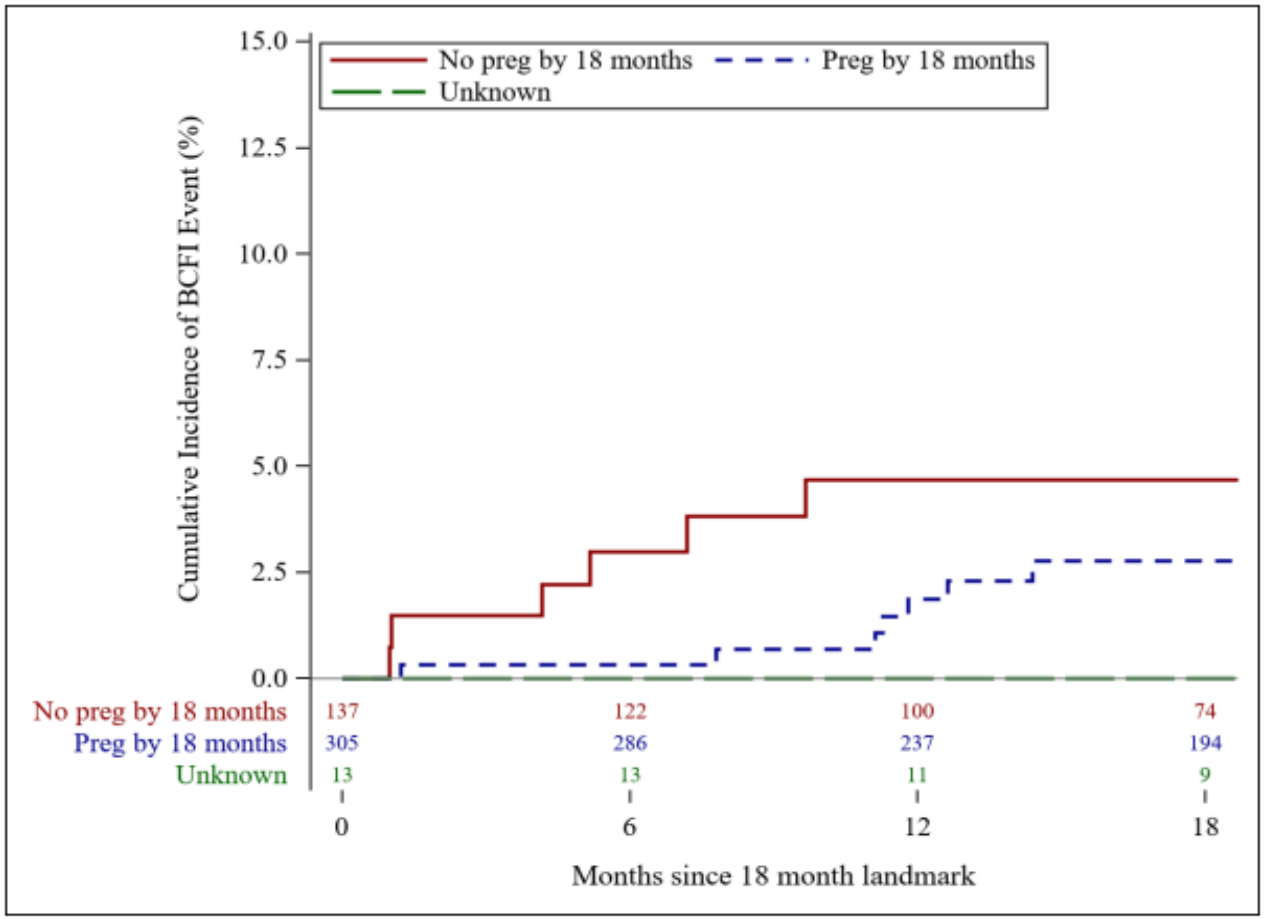
18-month Landmark Analysis



Time-dependent Cox Models

BCFI hazard ratios

(pregnant vs. not pregnant):

0.55 (95% CI: 0.28 to 1.06) – univariable

0.53 (95% CI: 0.27 to 1.04) – multivariable*

* including age, BMI, lymph node status, prior chemo, and prior AI

PREGNANCY OUTCOMES

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- 368 (74%) of the 497 women in the secondary endpoint population had at least one pregnancy (70% within 2 years) for a total of 507 pregnancies
- 317 had at least one live birth (64% of all women, 86% of those who became pregnant)

	N	% of 497	% of 368
Secondary endpoint population	497	100%	
At least one on trial pregnancy	368	**74%**	100%
At least one live birth (full-term or preterm)	317	**64%**	**86%**
At least one miscarriage	93	19%	25%
At least one elective abortion	16	3%	4%
At least one stillbirth/neonatal death	1/1	0.2% / 0.2%	0.3% / 0.3%

Note: 110 women had more than one pregnancy, and may contribute information to more than one row

- **Delivery**
  - Vaginal 66%
  - Cesarean section 34%
- **Pregnancy complications**
  - 11% of pregnancies
  - Most common:
    Hypertension/preeclampsia 3%
    Diabetes 2%

OFFSPRING OUTCOMES

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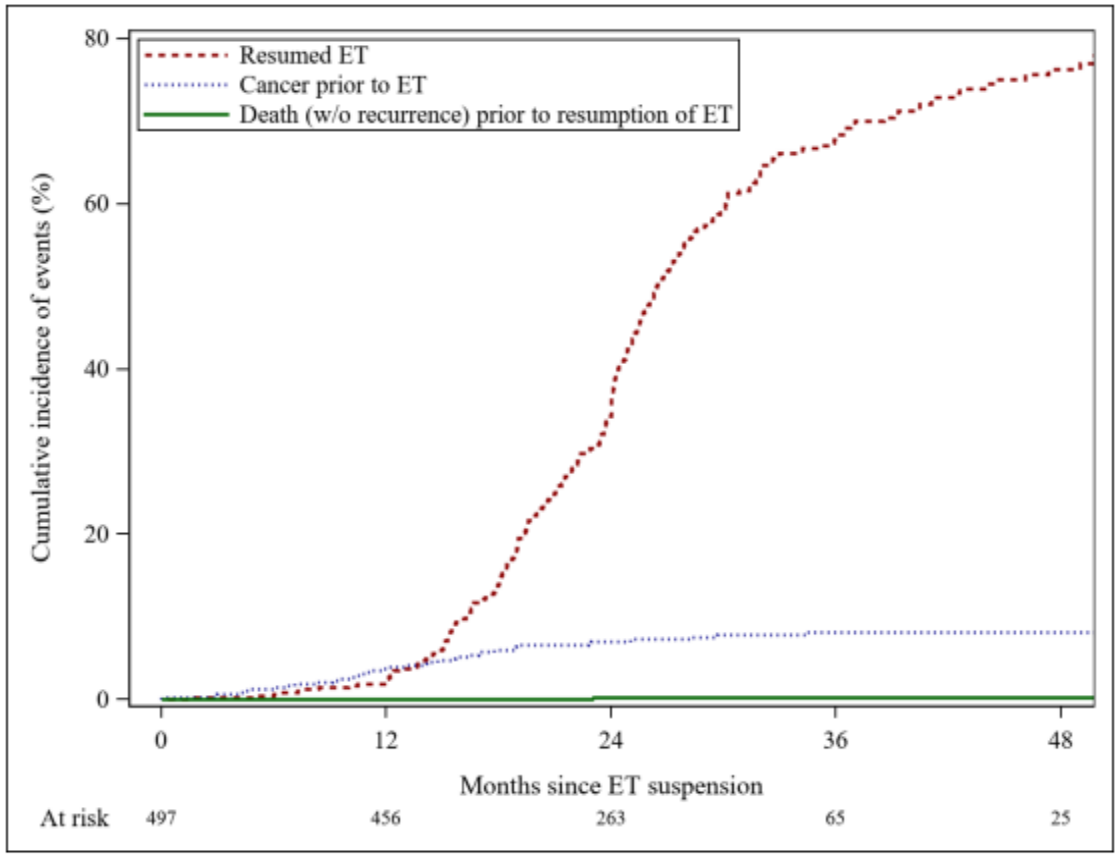
- 350 live births for the 317 women who had at least 1 live birth
- 335 singleton births and 15 sets of twins (365 offspring)
- 62% of 317 women reported breastfeeding

	N	%
Total offspring	365	100%
Low birth weight (<2500g)		
Yes	29	8%
No	**334**	**92%**
Missing/Unknown	2	0.5%
Birth defects		
Yes	8	2%
No	**350**	**96%**
Missing/Unknown	7	2%

ET RESUMPTION: COMPETING RISK ANALYSIS



Cumulative incidences at 48 months:

- 8% had cancer recurrence/death before resuming ET
- 76% resumed ET
- 15% had not yet resumed ET

79% of women disease-free at 2 years who have not yet resumed ET reported continuing pursuit of pregnancy, active/recent pregnancy or breastfeeding at most recent follow-up.

CONCLUSIONS

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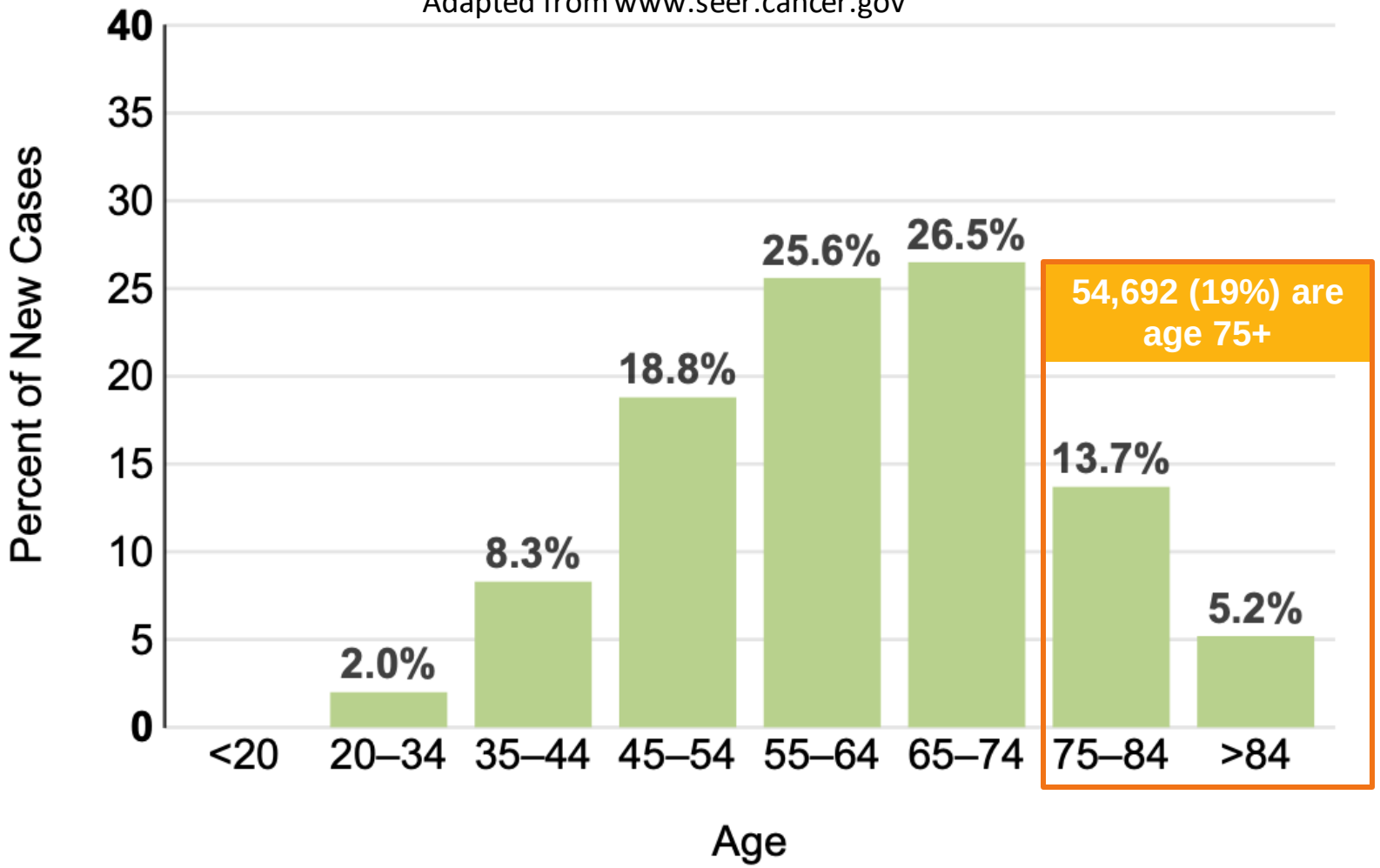
- In POSITIVE, temporary interruption of ET to attempt pregnancy among women who desire pregnancy does not impact short-term disease outcomes
- 74% of women had at least one pregnancy, most (70%) within 2 years
- Birth defects were low (2%), not clearly associated with treatment exposure
- Follow-up to 2029 planned to monitor ET resumption and disease outcomes
- **These data stress the need to incorporate patient-centered reproductive healthcare in the treatment and follow-up of young women with breast cancer**

≈20% of Breast Cancer Diagnoses Occur at Age ≥75

Total US cases estimated for 2022 = 287,850

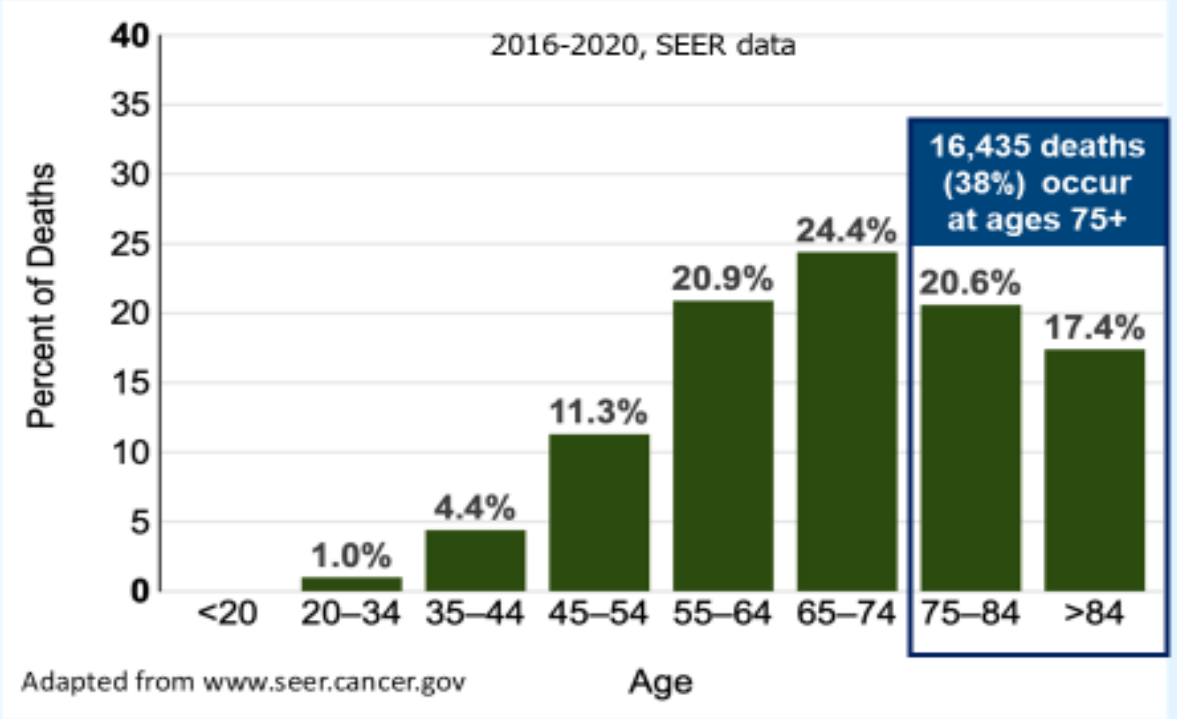
Adapted from www.seer.cancer.gov



San Antonio Breast Cancer Symposium®, December 6-10, 2022

...and Over 1/3 of Breast Cancer Deaths Occur at Age 75+

Total US breast cancer deaths estimated for 2022 = 43,250



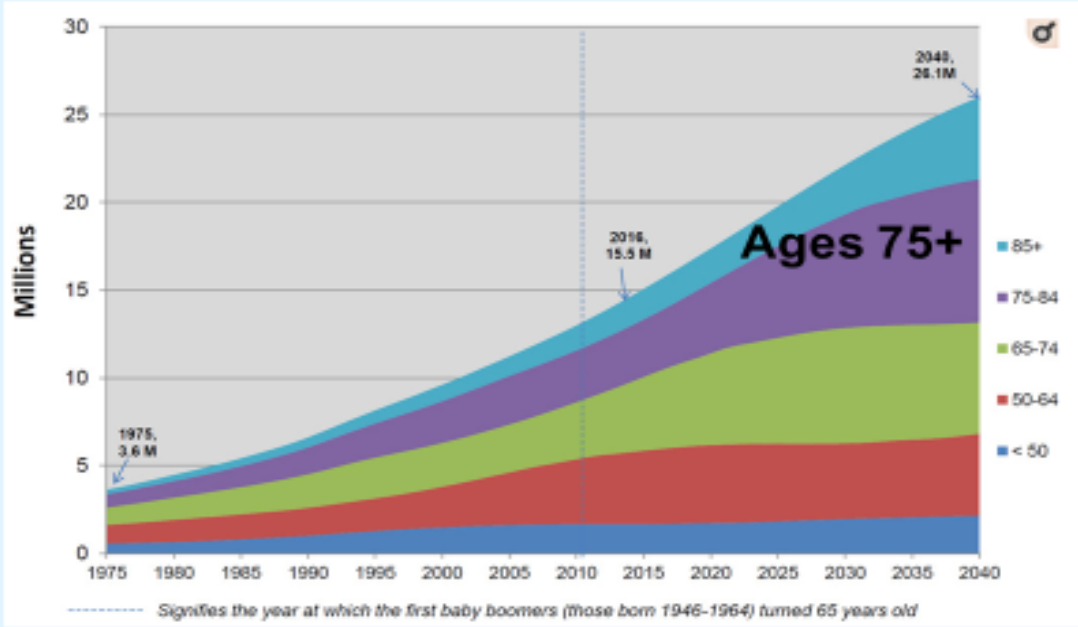
Due to…

- Late recurrences
- Prolonged courses of metastatic disease
- Under-treatment
- More toxicity, more functional decline → worse outcomes

*Improved survival outcomes over time have occurred at slower pace for older patients

Challenges also Exist in Survivorship

- Increased life expectancy => increased numbers older cancer survivors
- Treatment effects and sequelae require individualized care over a prolonged duration
- **We still do not know how to optimally treat and support older patients with cancer**
  - Clinical trial populations are younger and more fit



Bluethmann, Mariotto, & Rowland, Cancer Epidem and biomarkers, 2016

San Antonio Breast Cancer Symposium®, December 6-10, 2022

Caring for Older Adults with Cancer

Assess the patient…
-physical function, GA
-disease characteristics
-concerns and priorities
-life expectancy
-preferences

Calculate individualized…
-competing risk
-cancer recurrence risk
-toxicity risk
-benefits of therapy

Ji, et al.

Individualize treatment and interventions to mitigate toxicity and maintain physical function

Optimize support during treatment

Thrive in survivorship

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Benefits of Geriatric Assessment for Older Patients with Cancer

- Uncovers problems not detected by routine H&P
- Predicts for severe toxicity, hospitalizations, survival
- Helps clinicians with decision-making
- Helps teams expedite referrals
- Improves communication
- ++more

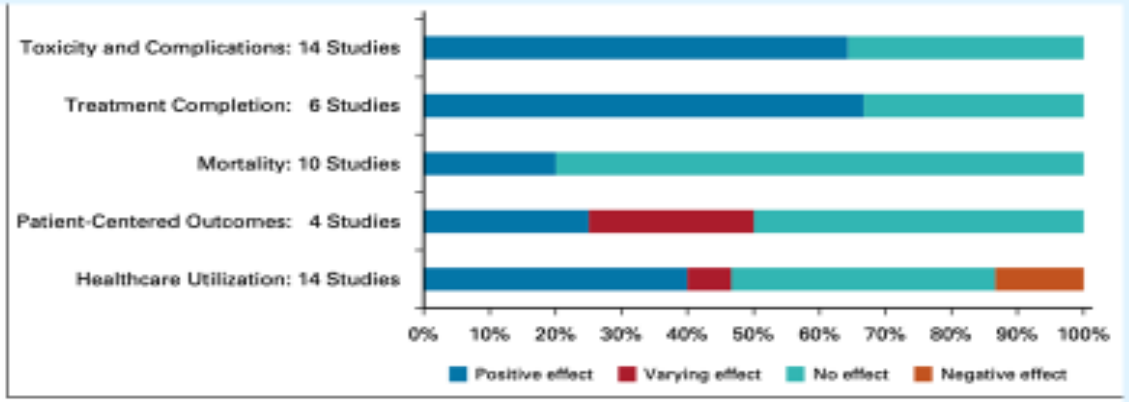


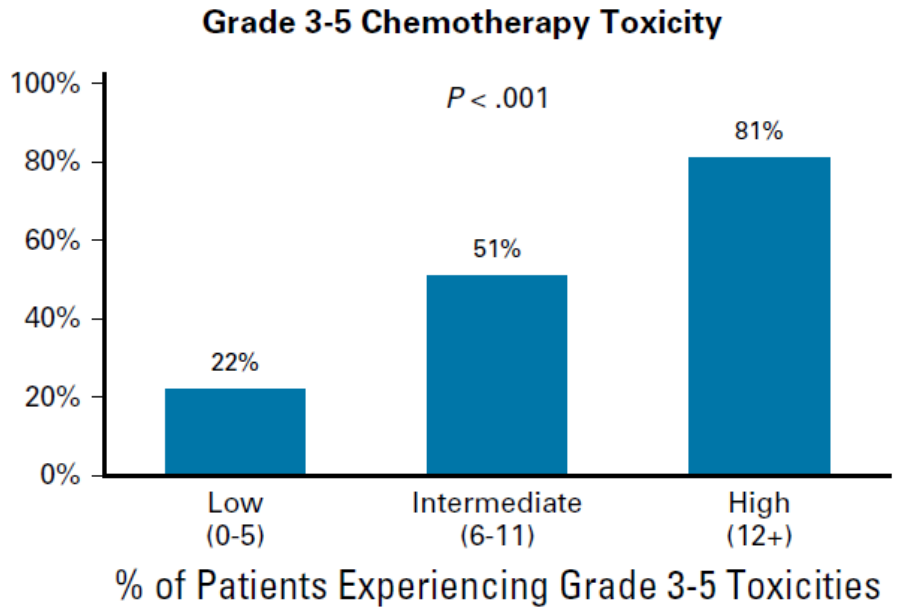
FIG 1. Effect of geriatric evaluation on course of treatment and different treatment outcomes—toxicity and complications, treatment completion, mortality, patient-centered outcomes, and healthcare utilization. Details per study in Table 2 and the Data Supplement.

2018 ASCO Guidelines for Geriatric Oncology: Systematic Review, adapted slide from Arti Hurria; Rosoft et al J Clin Oncol 2021

Using the GA to Develop and Validate 'CARG-BC'

TABLE 3. Multivariable Predictive Model

Risk Factors	Prevalence n (%)	With Grade 3-5 toxicity n (%)	OR (95% CI)	Score
Anthracycline	106 (37%)	63 (59%)	1.28 (0.62-2.67)	1
Stage II/III	173 (61%)	95 (55%)	1.87 (1.03-3.41)	3
Planned treatment duration > 3 months	149 (53%)	87 (58%)	2.90 (1.40-6.01)	4
Abnormal liver function	29 (11%)	18 (62%)	2.28 (0.93-5.63)	3
Abnormal hemoglobin	61 (21%)	37 (61%)	2.12 (1.05-4.30)	3
Fall in the past 6 months	26 (9%)	18 (69%)	3.04 (1.13-8.24)	4
Limited in walking more than 1 mile	110 (40%)	67 (61%)	2.31 (1.30-4.15)	3
Lack of someone to give good advice in a crisis	31 (11%)	19 (61%)	2.20 (0.91-5.33)	3



CARG-BC scores were associated with grade 3-5 toxicity, hospitalizations, dose modification, early treatment discontinuation, relative dose intensity

Magnuson et al J Clin Oncol, 2021

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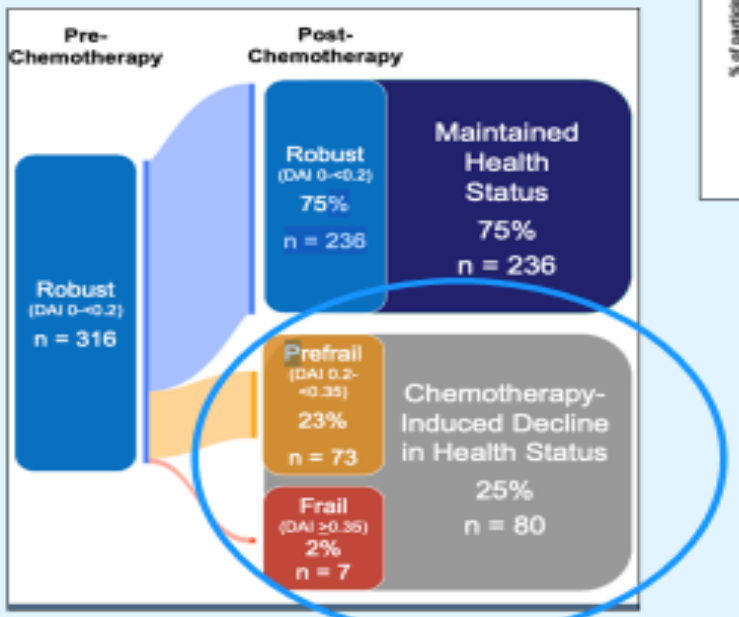
Jingran Ji, MD, et al. (City of Hope)

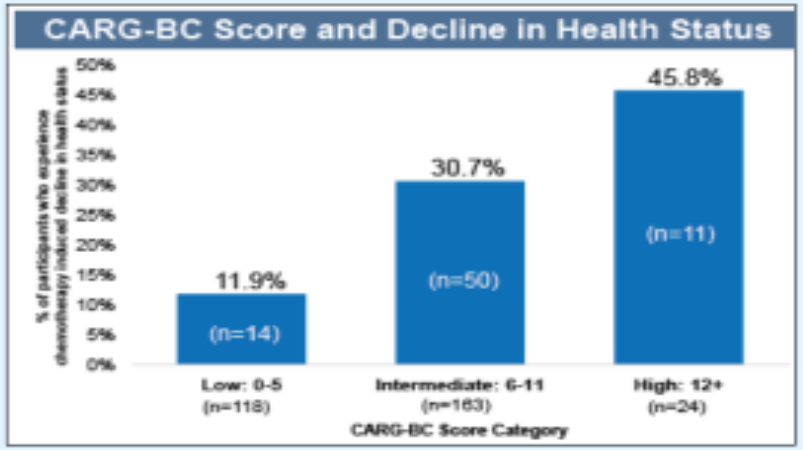
Association between the CARG-BC Score and Clinical Decline After Adjuvant Chemotherapy in Fit Older Adults with Breast Cancer: Results from Hurria Older PatiEnts (HOPE)

METHODS

- Secondary analysis of prospective cohort of pts age 65+ with stage I-III breast cancer receiving chemo who were fit per Deficit Accumulation Index (DAI)
- Primary endpoint = decline in health status, defined as change from robust to pre-frail or frail after chemotherapy

RESULTS





*Intermediate/high CARG-BC scores had 3-5x increased odds of decline, independent of BMI, age, CRP, IL-6

Ji, et al., cont.

STUDY CONCLUSIONS: Even 'fit' older patients are at high risk for health decline during chemotherapy. Baseline CARG-BC scores inform risk for decline, similar to how they inform risk for high grade chemotoxicity.

LIMITATIONS, CHALLENGES, AND CONTEXT:

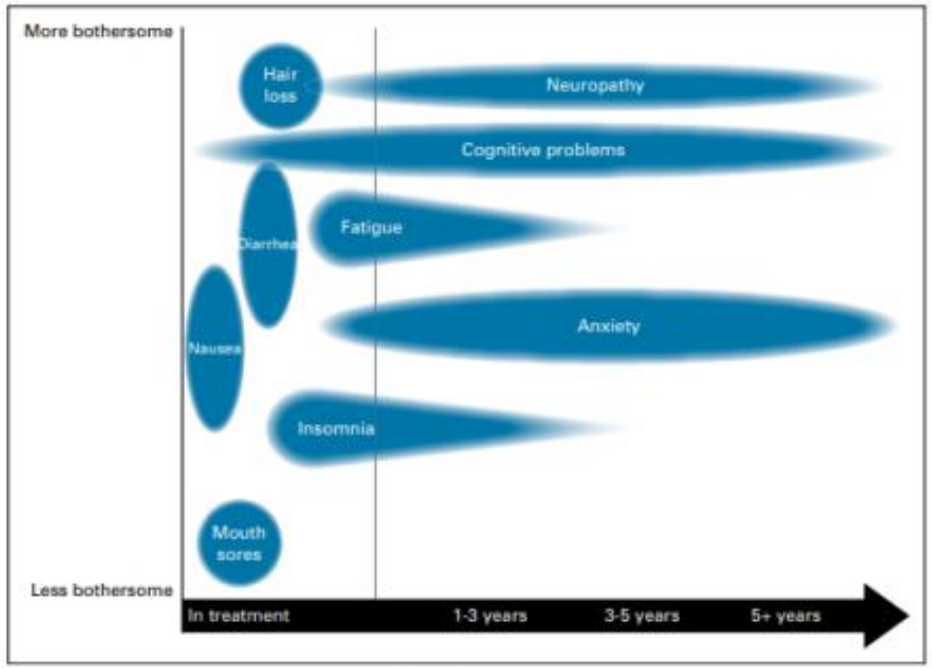
- Composite measure for outcome analyzed; specific domains not reported
- Substantial number (109) women were excluded for missing data
- Trajectory for those pre-frail/frail at baseline (small group) not presented
- Utilization of CARG-BC into clinical care is still not widely integrated
- Questions remain on how to mitigate health decline

Shi et al, J Gerontol A Biol Sci Med Sci 2019; Jones et al J Am Geriatrc Soc 2004

Comprehensive cancer care pathways

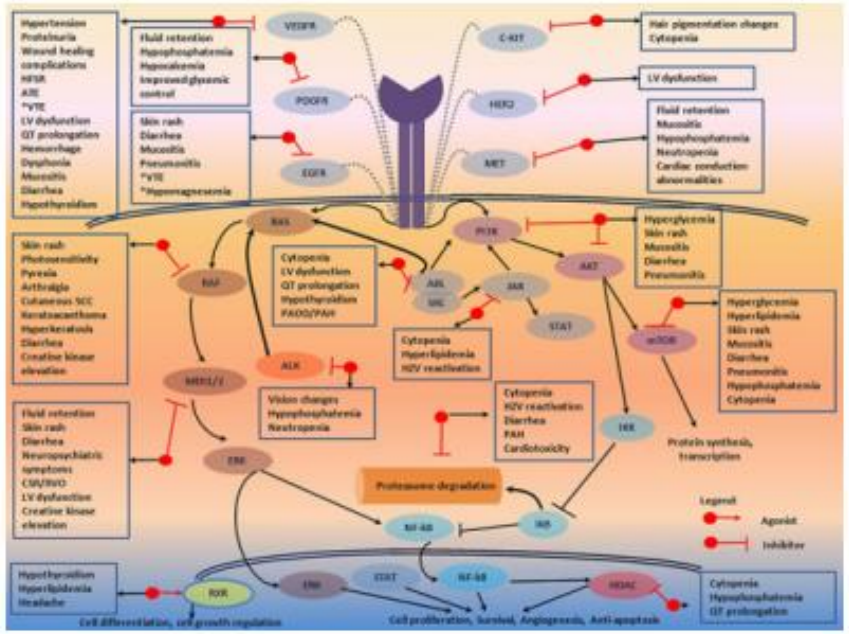
Supportive care needs evolve according to

Timing in the patient journey



Brauer E JOP 2018

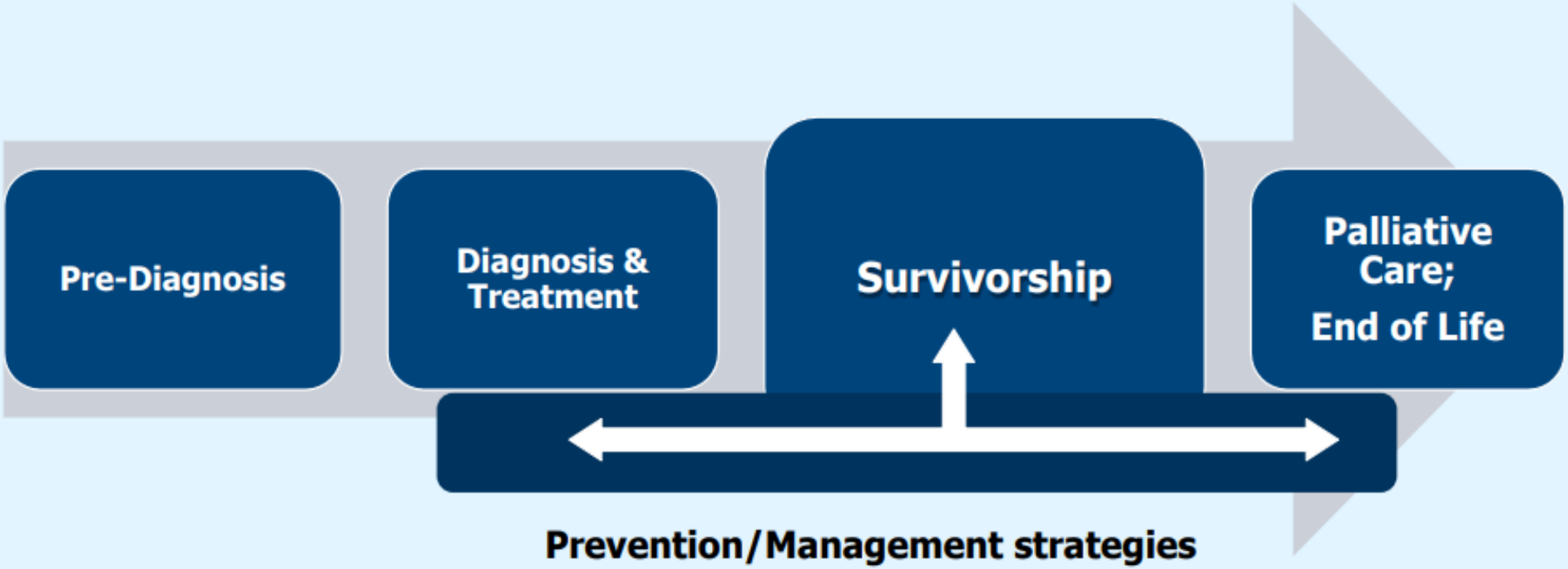
Treatment agents: novel therapies/AEs



Dy et al, CA A Cancer J Clinicians, 2013

Comprehensive cancer care pathways

Supportive care since diagnosis



Nekhlyudov L et al., JNCI 2019

- **PD8 04** The role of Yoga as a complementary therapy in women undergoing treatment for breast cancer: A randomized controlled trial. Nair et al.

Impact on clinical practice?

Trial is negative for primary endpoint but positive for symptom management

Reinforces prior data of the benefit of Yoga for improving overall QoL, fatigue, sleep disturbances and emotional distress

Outcomes	Illustrative comparative risks* (95% CI) Corresponding risk Yoga vs no therapy	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
Health-related quality of life (short-term) Self-assessed questionnaires Follow-up: 5-12 weeks	Mean health-related quality of life in intervention groups was **0.22 standard deviations higher** (0.06 to 0.38 higher)	675 (10 studies)	⊕⊕⊕○ **Moderate** [a]	SMD 0.22 (95% CI 0.04 to 0.40)
Health-related quality of life (medium-term) Self-assessed questionnaires Follow-up: 30-48 weeks	Mean health-related quality of life in intervention groups was **0.10 standard deviations higher** (0.23 lower to 0.42 higher)	146 (2 studies)	⊕⊕○○ **Low** [b,c]	SMD 0.10 (95% CI -0.23 to 0.42)
Depression (short-term) Self-assessed questionnaires Follow-up: 6-12 weeks	Mean depression in intervention groups was **0.13 standard deviations lower** (0.31 lower to 0.05 higher)	496 (7 studies)	⊕⊕○○ **Low** [b]	SMD -0.13 (95% CI -0.31 to 0.05)
Anxiety (short-term) Self-assessed questionnaires Follow-up: 2-12 weeks	Mean anxiety in intervention groups was **0.53 standard deviations lower** (1.1 lower to 0.04 higher)	346 (6 studies)	⊕○○○ **Very low** [b,d]	SMD -0.53 (95% CI -1.10 to 0.04)
Fatigue (short-term) Self-assessed questionnaires Follow-up: 6-12 weeks	Mean fatigue in intervention groups was **0.49 standard deviations lower** (0.75 to 0.23 lower)	883 (11 studies)	⊕⊕⊕○ **Moderate** [d]	SMD -0.48 (95% CI -0.75 to -0.20)
Fatigue (medium-term) Self-assessed questionnaires Follow-up: 30-48 weeks	Mean fatigue in intervention groups was **0.04 standard deviations lower** (0.36 lower to 0.29 higher)	146 (2 studies)	⊕⊕○○ **Low** [b,c]	SMD -0.04 (95% CI -0.36 to 0.29)
Sleep disturbances (short-term) Self-assessed questionnaires Follow-up: 4-12 weeks	Mean sleep disturbances in intervention groups were **0.25 standard deviations lower** (0.4 to 0.09 lower)	657 (6 studies)	⊕⊕⊕○ **Moderate** [a]	SMD -0.25 (95% CI -0.40 to -0.09)

Originality of design:

- Physical activity in control arm (need for details on adherence and PA regimen in full publication)
- Perhaps advantage of mind & body intervention vs body-only for symptom management (?)

Limitations:

- Unknown statistical assumptions
- Attrition

Cramer et al. Cochradane Database Syst Review 2017

PD8 04 The role of Yoga as a complementary therapy in women undergoing treatment for breast cancer
randomized controlled trial. Nair et

Impact on clinical practice?

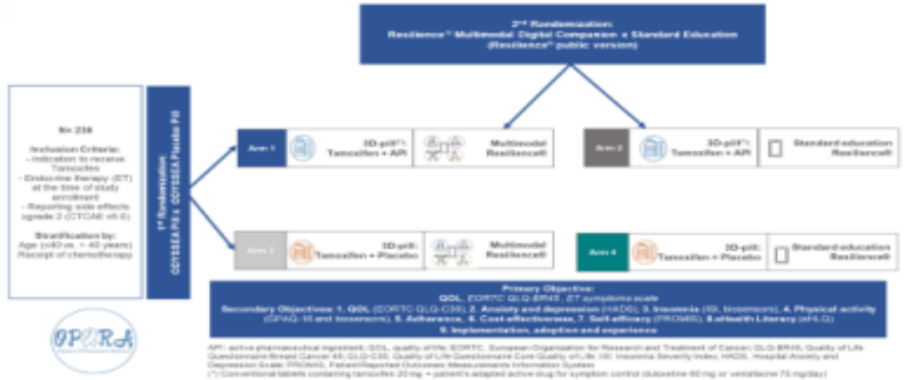
- Challenges:
  - Implement in clinical practice?
    (Retention, Standardized intervention [Coaches, script, Procedures] reimbursement?)

DigiYoga CaRe
(Nevo E et al BMJ Open 2022)

Primary aim:
Effect on CRF

Secondary endpoints:
- Efficacy on physical activity level,
- HRQoL and stress
- Effect on inflammatory response
- Cost-effectiveness including number of sick days and return to work
- Compliance of chemotherapy and adjuvant ET
- Feasibility of a totally digital solution regarding attendance, technical solutions and procedures
- Describe subjective experience

OPERA: (Personalized Digital Companion with self-management modules including Yoga)



GR Breast Cancer Survivorship Group 2022

- **PD8 06** Incidence of Acute and Persistent Clinically Meaningful Chemotherapy Induced Peripheral Neuropathy in Patients with Early-Stage Breast Cancer Receiving Taxane Therapy: SWOG S1714 (NCT# 03939481). Trivedi et al.

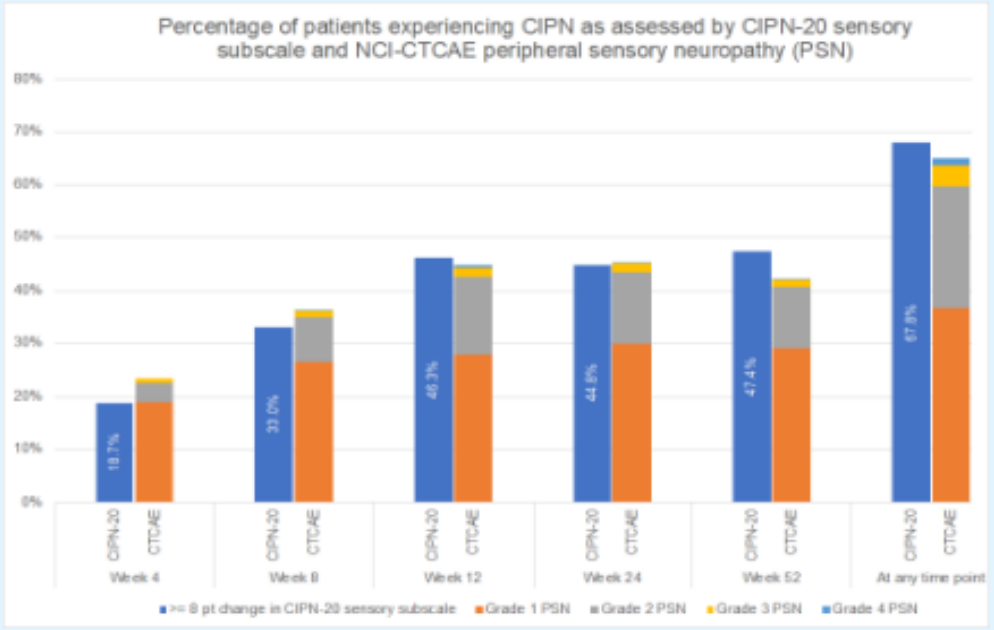
- **PD8 06** Incidence of Acute and Persistent Clinically Meaningful Chemotherapy Induced Peripheral Neuropathy in Patients with Early-Stage Breast Cancer Receiving Taxane Therapy: SWOG S1714 (NCT# 03939481). Trivedi et al.

METHODS	
Study type	▪ Prospective observational cohort study
Patient population	▪ 1336 patients diagnosed with stage I-III non-small cell lung, breast, or ovarian/fallopian tube/primary peritoneal cancer, starting treatment with a taxane-based regimen. 1198 (90.7%) of eligible participants had breast cancer
Primary objective	▪ The occurrence of clinically meaningful sensory neuropathy defined as an increase of 8 or more points between baseline and follow-up in the sensory neuropathy subscale of the CIPN-20.

- **PD8 06** Incidence of Acute and Persistent Clinically Meaningful Chemotherapy Induced Peripheral Neuropathy in Patients with Early-Stage Breast Cancer Receiving Taxane Therapy: SWOG S1714 (NCT# 03939481). Trivedi et al.

RESULTS

2/3: clinically meaningful sensory neuropathy symptoms at any time point
~50%: clinically meaningful sensory neuropathy symptoms after the end of the first year



Platforms to better understand and refine symptom prevention?

CANTO (CANcer Toxicities Cohort; NCT01993498)

- Prospective longitudinal cohort started in 2012
- **26 French comprehensive cancer centers**
- Dedicated **national network** sponsored by UNICANCER
- Reached inclusion of **12012** patients in 2018
- Ongoing/upcoming inclusion: age<40; new therapies; lung

Inclusion criteria:

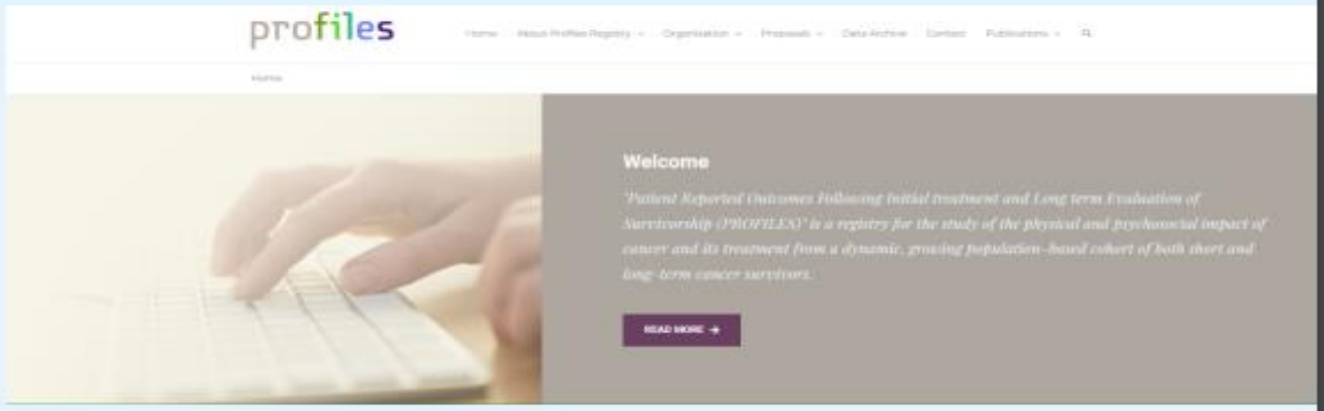
- 18+ years old diagnosis
- Stage I-II-III breast cancer
- Untreated at time of inclusion

Collected Information	Baseline	Follow-up after treatment					Long-term follow-up yearly for 5 years
	Diagnosis	Year-1	Year-2	Year-3	Year-4	Year-5	
Inclusion criteria							Prolonged and long-term toxicity Survival Outcomes
Signed informed consent							
Clinical examination^							
Blood tests							
Paraclinical examination							
Questionnaires (PROs)*							
Biological samples							

Completion of treatment (surgery, chemo, or radio)

*Includes detailed assessment of supportive care consultations

*EORTC-QLQ C30, BR23, FA12, GPAQ-16, HADS, SF-12, IOCv2, social and financial reports



Comprehensive cancer care pathways for toxicity management:

Non-pharmacological strategies:

Advantages:

- Can deal simultaneously with a range of symptoms
- Sustainable in the long-term
- **Safe and no need of monitoring of additional side-effects**

Challenges:

- Team Medicine, implementation and adoption

Adapted from Franzoi MA et al, Lancet Oncol 2021

- **PD8 04** The role of Yoga as a complementary therapy in women undergoing treatment for breast cancer: A randomized controlled trial. Nair et al.

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METHODS	
Study type	▪ Randomized controlled trial
Patient population	▪ 850 women with non-metastatic breast cancer during and after standard treatment, were randomized to yoga and conventional exercise (YCE) versus conventional exercise only (CE).
Intervention	▪ YCE versus CE only.
Primary endpoint	▪ Disease-free survival

- **PD8 04** The role of Yoga as a complementary therapy in women undergoing treatment for breast cancer: A randomized controlled trial. Nair et al.

RESULTS

Median follow-up 80 months: YCE VS. CE

- DFS 80% vs 76.7% (HR= 0.85, 95% CI= 0.64-1.14, p=0.28)
- OS 85.4% vs 83.1% (HR= 0.86, 95%CI = 0.61-1.21, p=0.38)

- Improved physical (p=0.043) and emotional function (0.017), fatigue (p=0.002), pain (p=0.031), appetite loss (< 0.001) arm symptoms (0.035) and systemic therapy side effects (0.036) reduced at 6-9mo in YCE, mostly persisted over time

PD8 04 The role of Yoga as a complementary therapy in women undergoing treatment for breast cancer
randomized controlled trial. Nair et

Impact on clinical practice?

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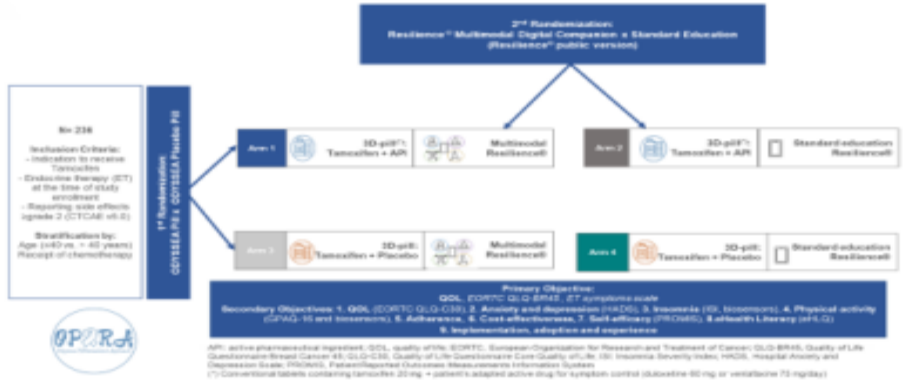


GR Breast Cancer Survivorship Group 2022

- **PD8 05** Effectiveness of Electroacupuncture Versus Auricular Acupuncture in Reducing Pain and Improving Quality of Life in Breast Cancer Survivors with Chronic Musculoskeletal Pain. Bao et al.

- **PD8 05** Effectiveness of Electroacupuncture Versus Auricular Acupuncture in Reducing Pain and Improving Quality of Life in Breast Cancer Survivors with Chronic Musculoskeletal Pain. Bao et al.

METHODS	
Study type	▪ 3-arm, parallel, single center randomized trial
Patient population	▪ 360 cancer survivors, 165 (46%) patients with previous breast cancer diagnosis
Intervention	▪ Electroacupuncture Versus Auricular Acupuncture
Primary endpoint	▪ Change in mean Brief Pain Inventory (BPI) pain intensity from baseline to week 12
Statistical analyses	▪ Constrained linear mixed model analyses, which constrained all arms to have a common pre-randomization baseline mean. Model-based mean estimates at weeks 12 and 24 were compared between arms using model contrasts. For the step 1: 80% power to detect a standardized mean difference of 0.48 between electroacupuncture vs usual care and auricular acupuncture vs usual care. Assuming an SD between 2 and 3, this effect size translates to a difference of 1 to 1.5 points on the 0-10 BPI pain severity scale. For the step 2 comparison, 80% power to find auricular acupuncture noninferior to electroacupuncture with respect to change in BPI pain severity score within a margin of one-third change-score SDs, assuming a 1-sided significance threshold of $P < .05$

- **PD8 05** Effectiveness of Electroacupuncture Versus Auricular Acupuncture in Reducing Pain and Improving Quality of Life in Breast Cancer Survivors with Chronic Musculoskeletal Pain. Bao et al.

RESULTS

- 10-weeks Personalized Electroacupuncture (EA) > Auricular Acupuncture (AA) at reducing pain severity at both week 12, (-0.90 [-1.45, -0.36], p=0.001) and week 24 (-0.82, [-1.38, -0.27], p=0.004).
- Mild toxicities were reported, more patients dropped out of the AA arm due to ear pain

- **PD8 05** Effectiveness of Electroacupuncture Versus Auricular Acupuncture in Reducing Pain and Improving Quality of Life in Breast Cancer Survivors with Chronic Musculoskeletal Pain. Bao et al.

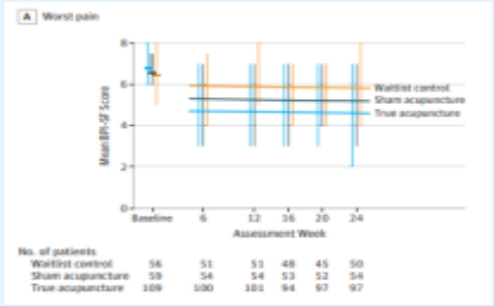
Impact on clinical practice?

1) Auricular Acupuncture is not equal to Electroacupuncture in BC survivors:

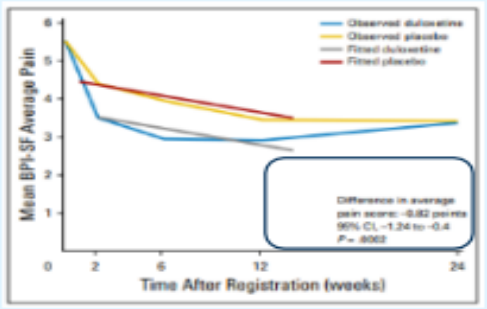
Similar to primary results published in Jama Oncology 2021 (Mao et al) - Pan tumor

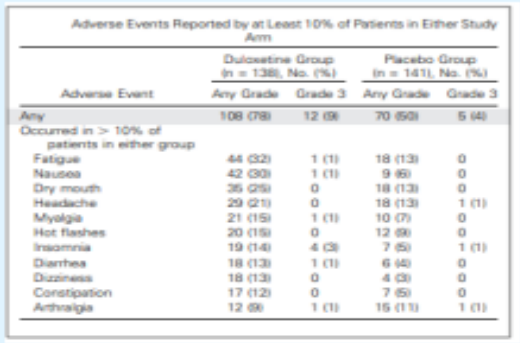
2) Acupuncture is an alternative for Musculoskeletal Pain induced by ET

Around 50% of study population in PEACE using adjuvant ET



Hershman D. Jama 2018





Adverse Events Reported by at Least 10% of Patients in Either Study Arm

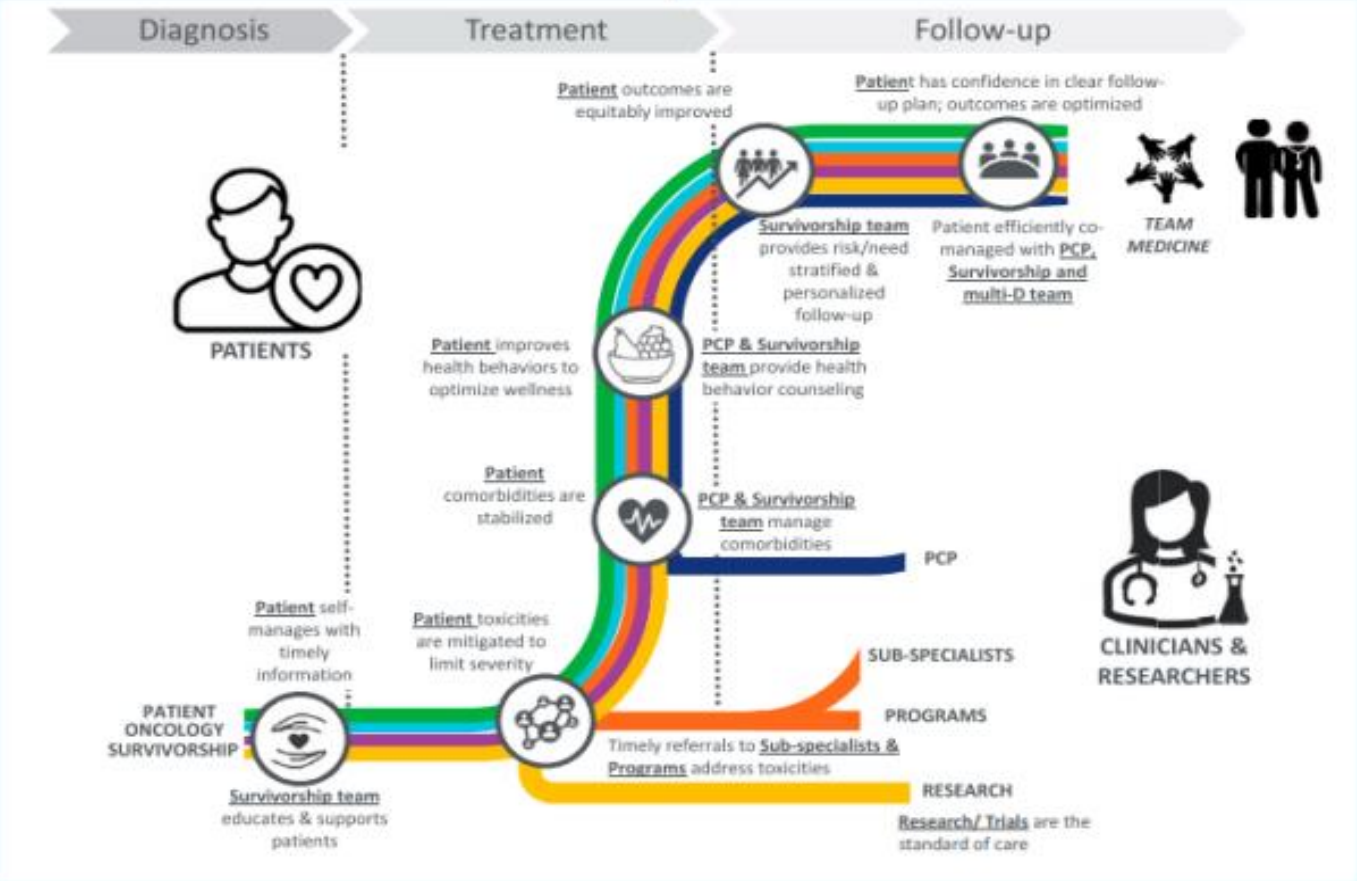
Adverse Event	Duloxetine Group (n = 138), No. (%)		Placebo Group (n = 141), No. (%)	
	Any Grade	Grade 3	Any Grade	Grade 3
Any	108 (78)	12 (9)	70 (50)	5 (4)
Occurred in > 10% of patients in either group				
Fatigue	44 (32)	1 (1)	18 (13)	0
Nausea	42 (30)	1 (1)	9 (6)	0
Dry mouth	35 (25)	0	18 (13)	0
Headache	29 (21)	0	18 (13)	1 (1)
Myalgia	21 (15)	1 (1)	10 (7)	0
Hot flashes	20 (15)	0	12 (9)	0
Insomnia	19 (14)	4 (3)	7 (5)	1 (1)
Diarrhea	18 (13)	1 (1)	6 (4)	0
Dizziness	18 (13)	0	4 (3)	0
Constipation	17 (12)	0	7 (5)	0
Arthralgia	12 (9)	1 (1)	15 (11)	1 (1)

Henry H. JCO 2017

3) Implementation Challenges: Standardized procedure, coordinated care, reimbursement

Comprehensive cancer care pathways for preventing and managing toxicities

Coordinated and personalized care



Alfano C. ASCO Ed Book 202

Questions