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Can we adapt the standard according to patient's health status?

Can we adapt the surgical standards according to the patient's health status?

SURGERY

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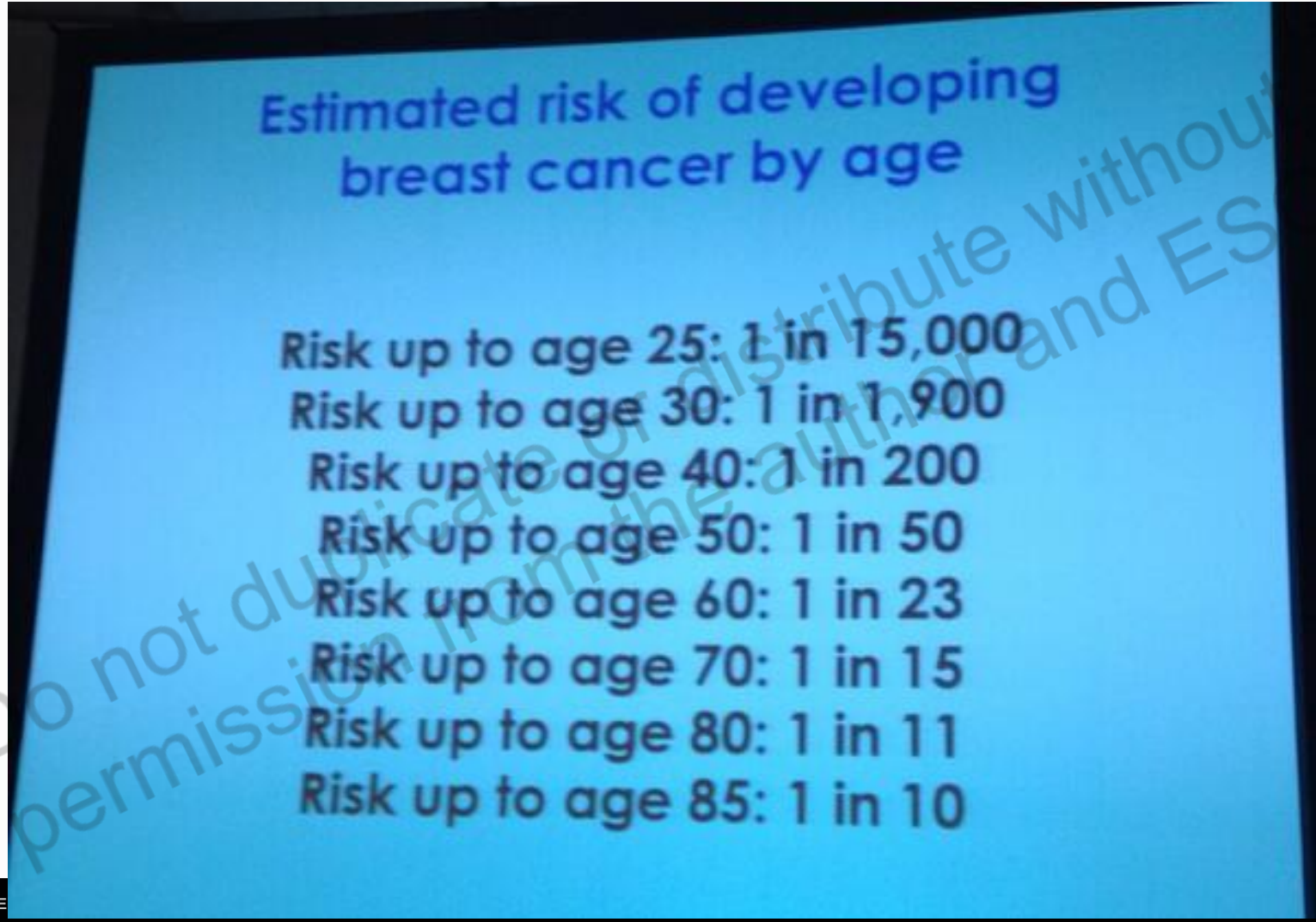
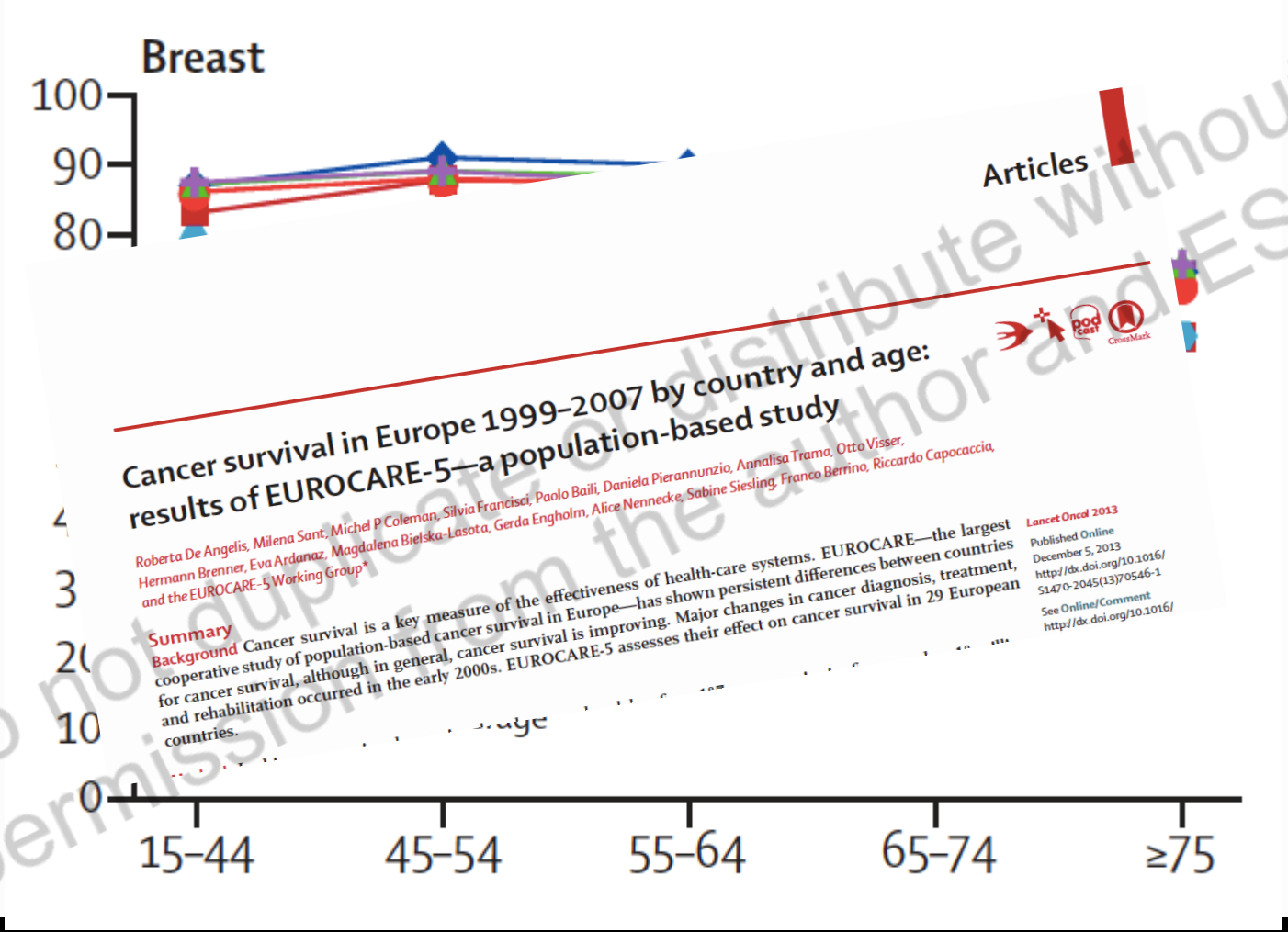




Cancer survival in Europe 1999–2007 by country and age: results of EUROCARE-5—a population-based study

Roberta De Angelis, Milena Sant, Michel P Coleman, Silvia Francisci, Paolo Baili, Daniela Pierannunzio, Annalisa Trama, Otto Visser, Hermann Brenner, Eva Ardanaz, Magdalena Bielska-Lasota, Gerda Engholm, Alice Nennecke, Sabine Siesling, Franco Berrino, Riccardo Capocaccia, and the EUROCARE-5 Working Group*

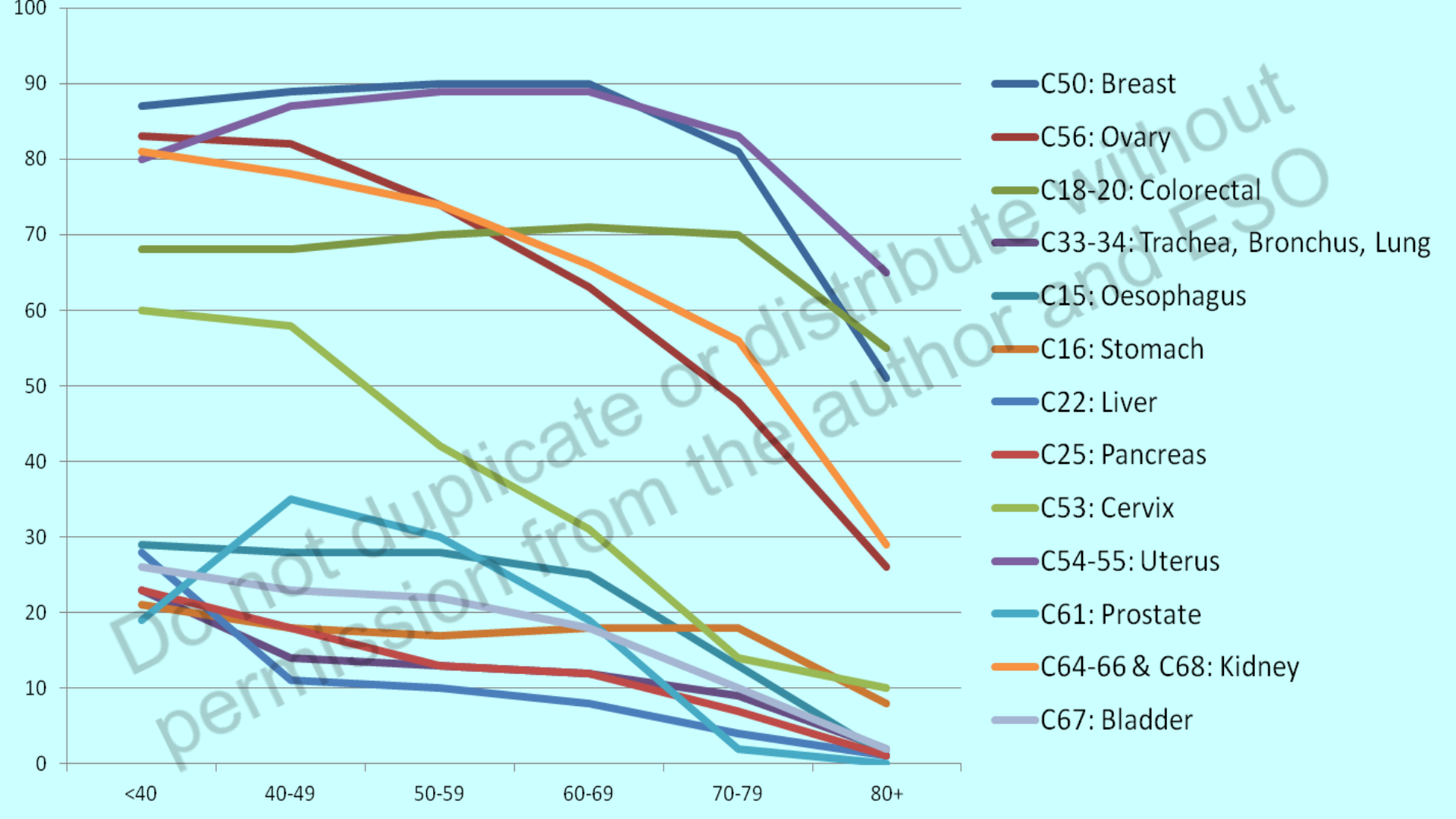
Lancet Oncol 2013
Published Online December 5, 2013 http://dx.doi.org/10.1016/S1470-2045(13)70546-1
See Online/Comment http://dx.doi.org/10.1016/

Summary

Background Cancer survival is a key measure of the effectiveness of health-care systems. EUROCARE—the largest cooperative study of population-based cancer survival in Europe—has shown persistent differences between countries for cancer survival, although in general, cancer survival is improving. Major changes in cancer diagnosis, treatment, and rehabilitation occurred in the early 2000s. EUROCARE-5 assesses their effect on cancer survival in 29 European countries.

BC is rather easy to cure (80-90% cure rate)
Despite this the outcome is poor for older women

Hard to blame medical/radiation-oncologists:
a SURGICAL failure !!!



Surgery: 1st choice treatment

Adjuvant chemotherapy and survival in women aged 70 years and older with triple-negative breast cancer: a Swedish population-based propensity score-matched analysis

Slavica Janeva, Chenyang Zhang, Anikó Kovács, Toshima Z Parris, Jennifer A Crozier, Christopher M Pezzi, Barbro Linderholm, Riccardo A Audisio, Roger Olofsson Bagge

Summary

Background Triple-negative breast cancer (TNBC) is an aggressive form of breast cancer associated with poor survival, in which adjuvant systemic treatments are limited to chemotherapy. Due to competing mortality risks and comorbidities, older patients with TNBC are often undertreated with adjuvant chemotherapy, and clinical trials on this problem are scarce, despite a growing patient population. This study aimed to assess outcomes for patients aged

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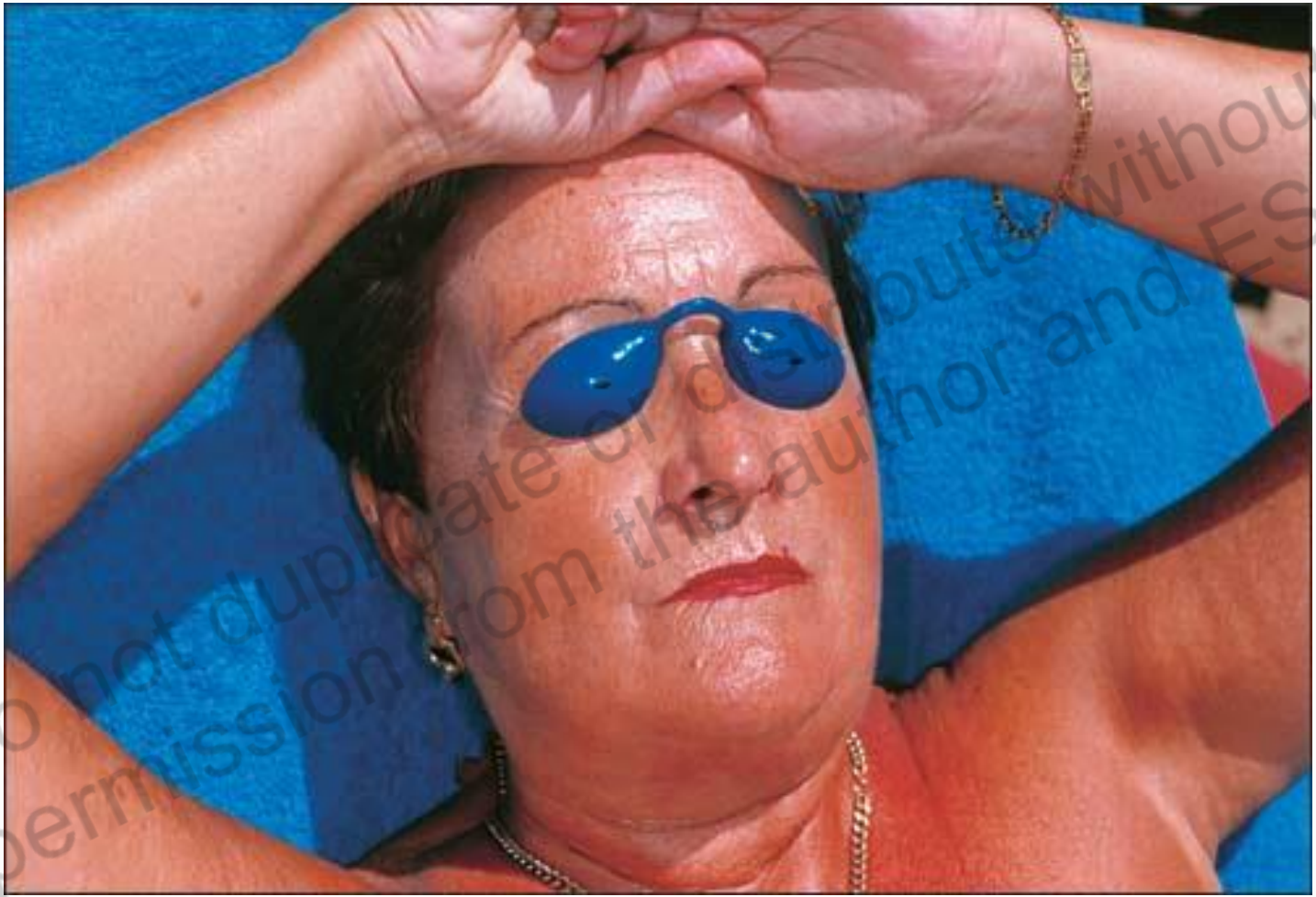
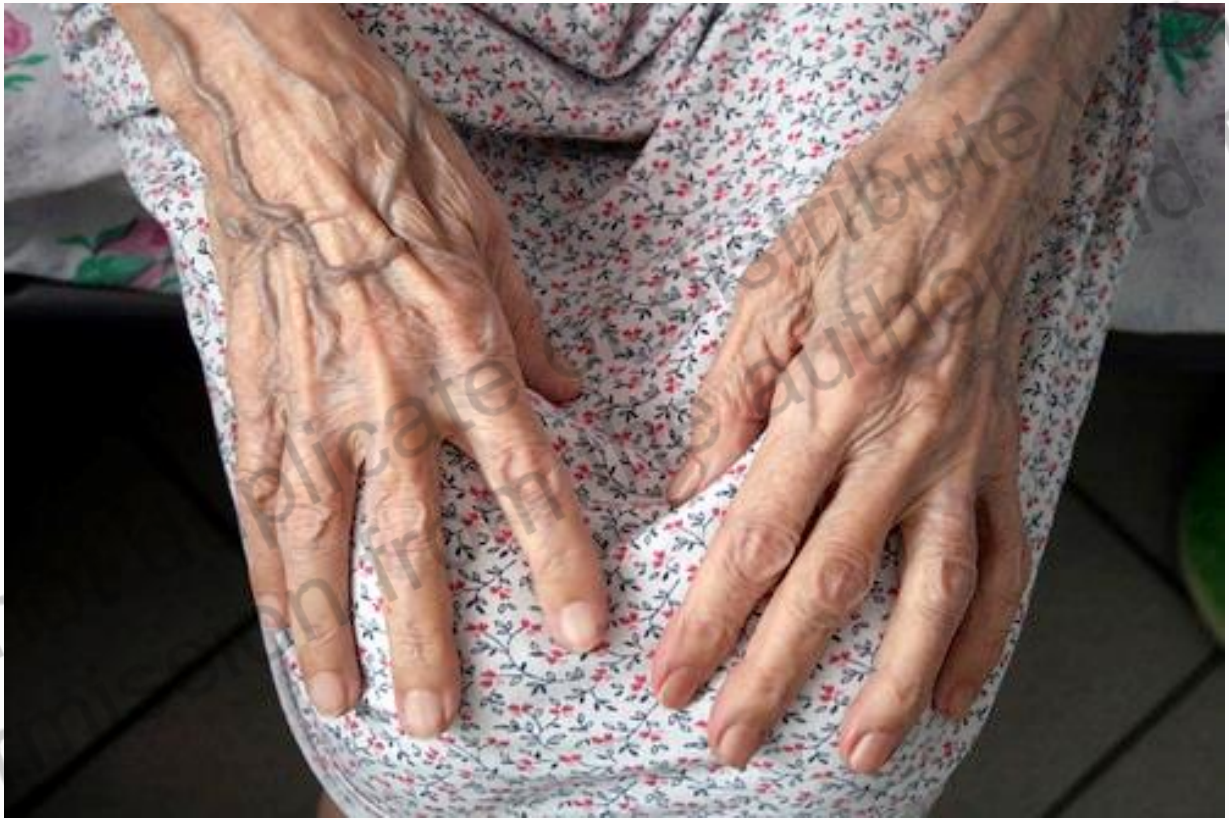


patient’s preference



“Precision” Surgery

patient centred

discuss ALL available options (including no-surgery)

assess frailty & optimise patient

explain/engage with pts decision-making

The Age Gap Study (3,500 women >age 70)

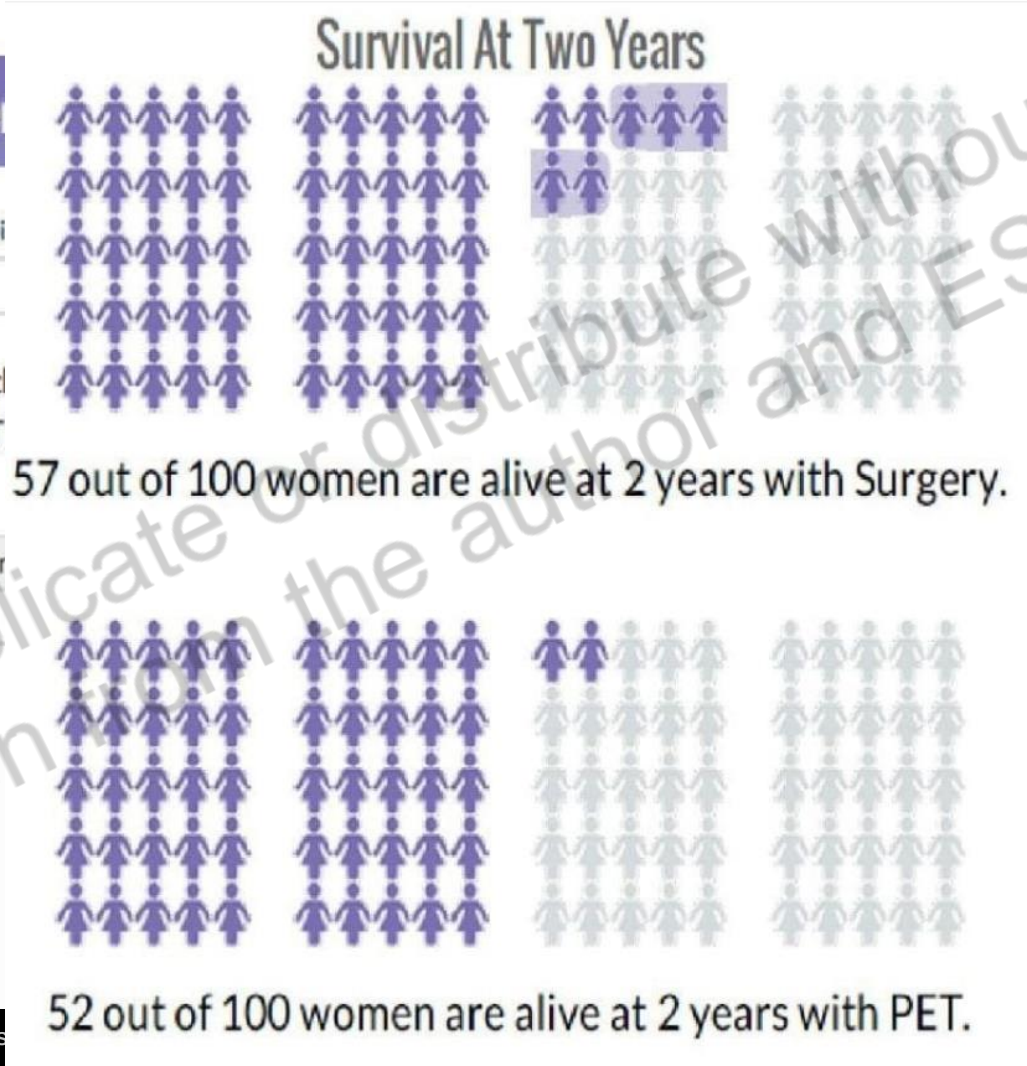
https://cancerworld.net/bridging-the-age-gap-in-breast-cancer-chemotherapy-and-quality-of-life/

Age Gap Decision Tool: Surge

Age	Tumour grade	Tumour size	Di
87	3	15mm	

Based on the details above, researc
Primary Endocrine Therapy (PET

Age	Tumour grade	Tumour size	Disease r
87	3	15mm	



Special cases:

- mastectomy vs WLE+RT > Greece: 3,000 islands
- breast reconstruction/remodelling

personalised treatment at all times !!!

Q: Can we adapt the standard according to the patient's health status?

- Engage with patients: appreciate expectations & rule out fears
- Appreciate frailty vs life expectancy
- Taylor surgical treatment

A: Sure we can – we should be doing all the time, no matter the age!

Recommendation 1

- For patients age ≥ 70 years with clinically node-negative (T1N0) early-stage invasive breast cancer, that is hormone receptor–positive and human epidermal growth factor receptor 2 (HER2)–negative, SLNB is not required. This supported by the Choosing Wisely statement released on July 12, 2016, and updated on June 20, 2019, by the Society of Surgical Oncology[8] that stated, "Don't routinely use sentinel node biopsy in clinically node negative women ≥ 70 years of age with early stage hormone receptor positive, HER2 negative invasive breast cancer" if they will be treated with hormonal therapy. If omission of SLNB is considered, a consultation with a medical oncologist can be considered before surgery to discuss hormonal therapy (Type: informal consensus; benefits outweigh harms; Evidence quality: insufficient; Strength of recommendation: moderate).

...ent of the Axilla in Early-Stage Breas...
...alth (Cancer Care Ontario) and

...MEd[3]; ...King, MD[8]; ...[13]

...S;

abstract

PURPOSE To provide recommendations... treatment (surgical and radiotherapeutic) of the...

METHODS Ontario Health (Cancer Care Ontario) and ASCO ... develop evidence-based recommendations informed by a systematic re...

RESULTS This guideline endorsed two recommendations of the ASCO 2017 guideli... lymph node biopsy in patients with early-stage breast cancer and expanded on that guide... mendations for radiotherapy interventions, timing of staging after neoadjuvant chemotherapy (NAC), mapping modalities. Overall, the ASCO 2017 guideline, seven high-quality systematic reviews, 54 unique studies, and 65 corollary trials formed the evidentiary basis of this guideline.

JAMA Oncology | Original Investigation

Trends in Reoperation After Initial Lumpectomy for Breast Cancer

Addressing Overtreatment in Surgical Management

Monica Morrow, MD; Paul Abrahamse, MA; Timothy P. Hofer, MD; Kevin C. Ward, PhD, MPH; Ann S. Hamilton, PhD; Allison W. Kurian, MD, MSc; Steven J. Katz, MD, MPH; Reshma Jagsi, MD, DPhil

IMPORTANCE Surgery after initial lumpectomy to obtain more widely clear margins is common and may lead to mastectomy.

OBJECTIVE To describe surgeons' approach to surgical margins for invasive breast cancer, and changes in postlumpectomy surgery rates, and final surgical treatment following a 2014 consensus statement endorsing a margin of "no ink on tumor."

DESIGN, SETTING, AND PARTICIPANTS This was a population-based cohort survey study of 7303 eligible women ages 20 to 79 years with stage I and II breast cancer diagnosed in 2013 to 2015 and identified from the Georgia and Los Angeles County, California, Surveillance, Epidemiology, and End Results registries. A total of 5080 (70%) returned a survey. Those with bilateral disease, missing stage or treatment data, and with ductal carcinoma in situ were excluded, leaving 3729 patients in the analytic sample; 98% of these identified their

Author Audio Interview

Supplemental content

Q1:

a) Elderly women, the group at highest risk for developing breast cancer, are treated fairly and successfully.

b) Cancer-specific outcomes are very encouraging.

c) Patient-centred treatment has to be pursued.

d) It is easy to understand patients' needs and targets.

Q2:

a) There is no difference between young and senior breast cancer patients and they all should be treated as per protocol.

b) Surgery should be avoided whenever possible.

c) Frailty assessment and patient's aims should be taken into account when offering tailored treatment.

d) Bringing older BC patients to theatre diminishes their average survival.

Adapting radiotherapy to health status in older breast cancer patients

Professor Ian Kunkler

University of Edinburgh

Disclosures

I have no financial disclosures or conflicts of interest

Health factors and adapting RT for older patients

Health factors

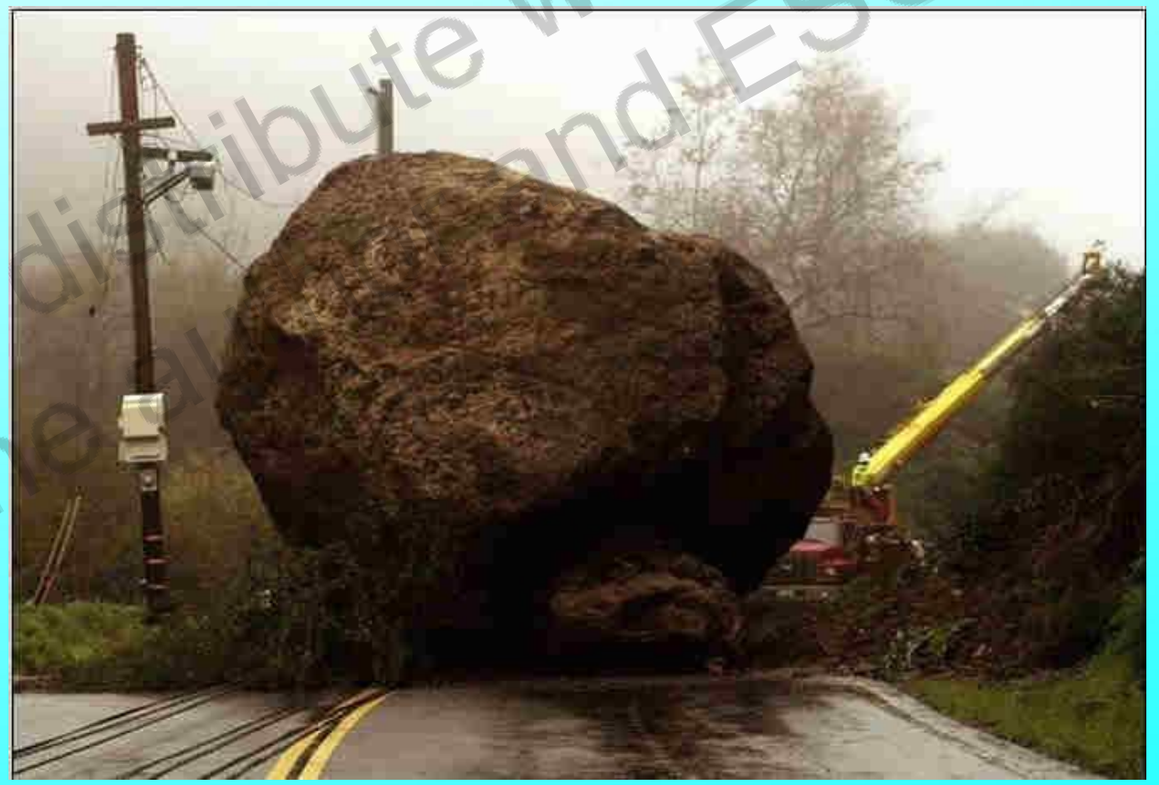
- Frailty
- Cardiac disease

Adaptations

- RT techniques to reduce toxicity
- Omission of adjuvant RT
- Hypofractionation
- Partial breast irradiation
- Future directions

Barriers to tailoring breast RT to health status

- Lack on integration of training in geriatric oncology into MDTs
- Few geriatric oncologists
- Limited no of centres applying any form of Comprehensive Geriatric Assessment (CGA)
- Additional resources needed for CGA

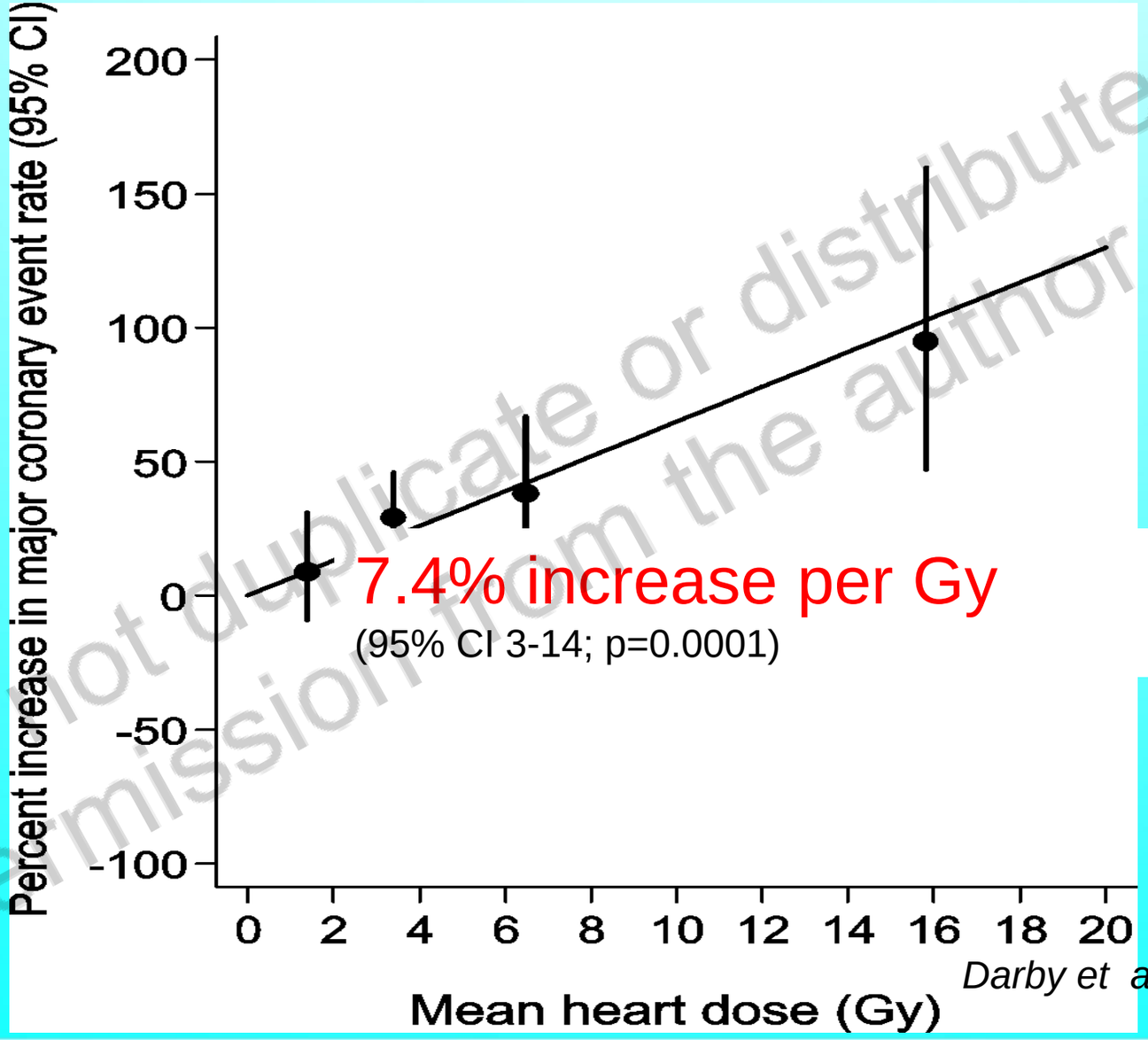


Risk stratification and geriatric assessment (Rostoft et al JCO 2021;39:2058-65)

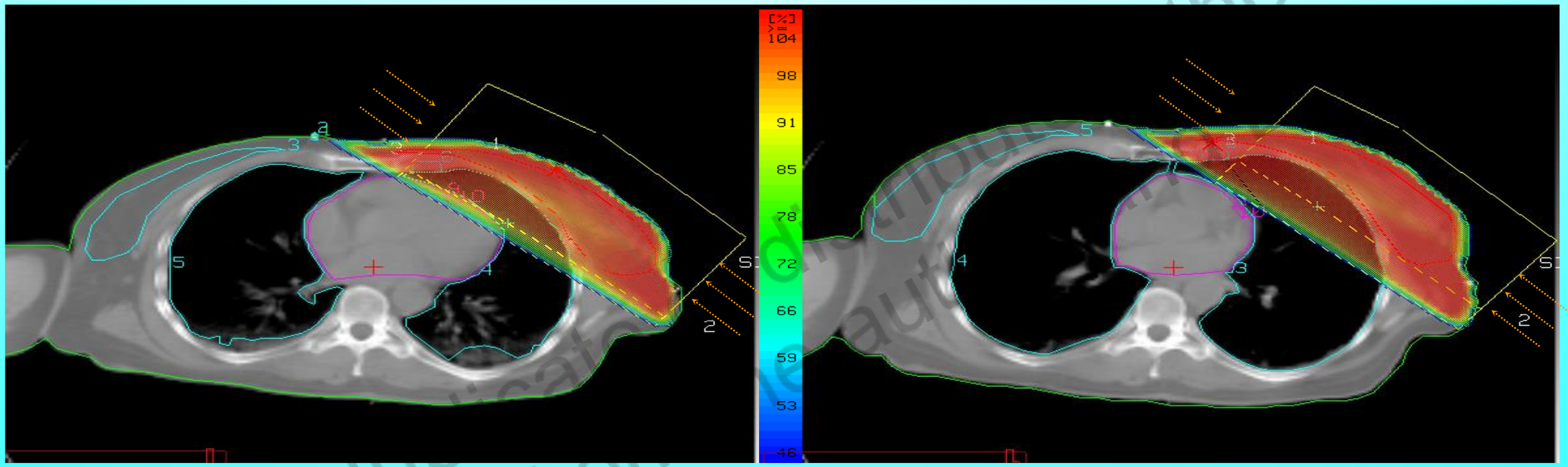
- Geriatric assessment improves prognostication and risk stratification
- There are two validated prediction models of severe toxicity with chemotherapy in older adults, superior to performance status (Hurria A et al,JCO 2011;29:3457-65; Extermann et al, Cancer 2012;118:3377-86)

At present there is no similar validated risk stratification tool in radiation oncology

Risks of RT induced cardiotoxicity



Darby et al NEJM 2013; 368:987-98



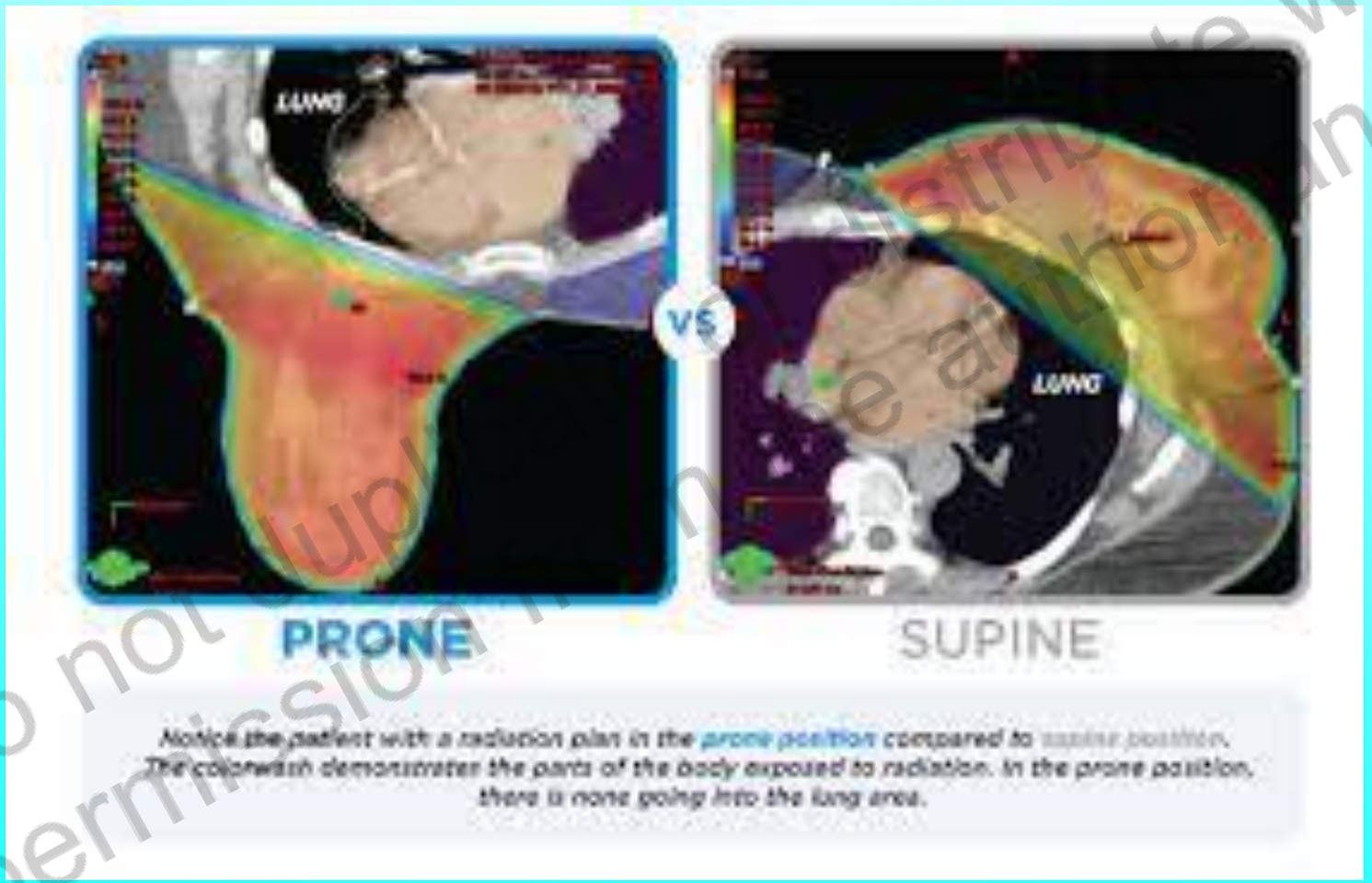
Expiration Gating (EG)

Deep Inspiration Breath Hold (DIBH)

Margins designed from population based mean excusions

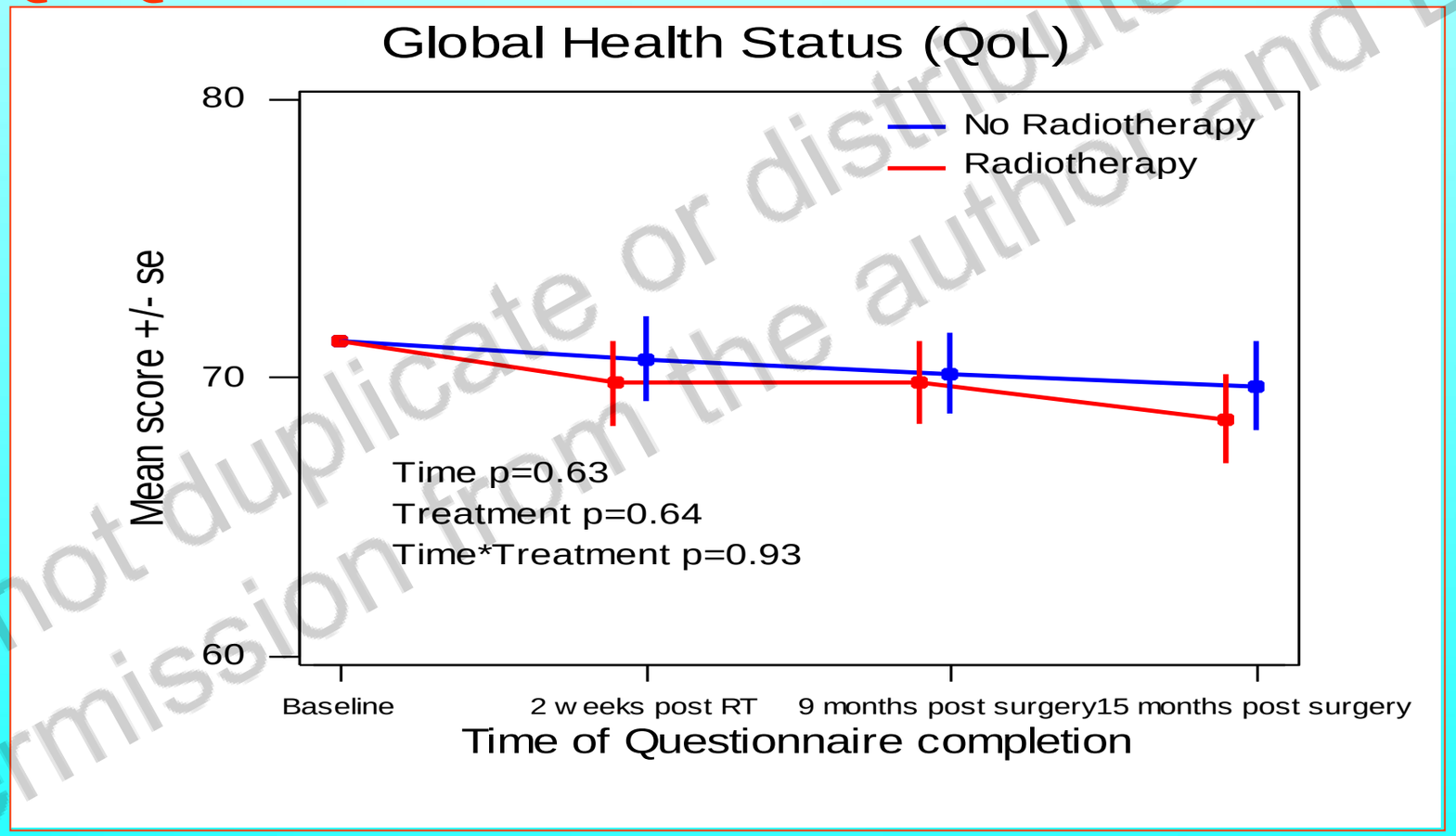
(Excursion FB: 2.5 mm, Margin 10 mm /CTV – field edge)

Prone radiotherapy planning



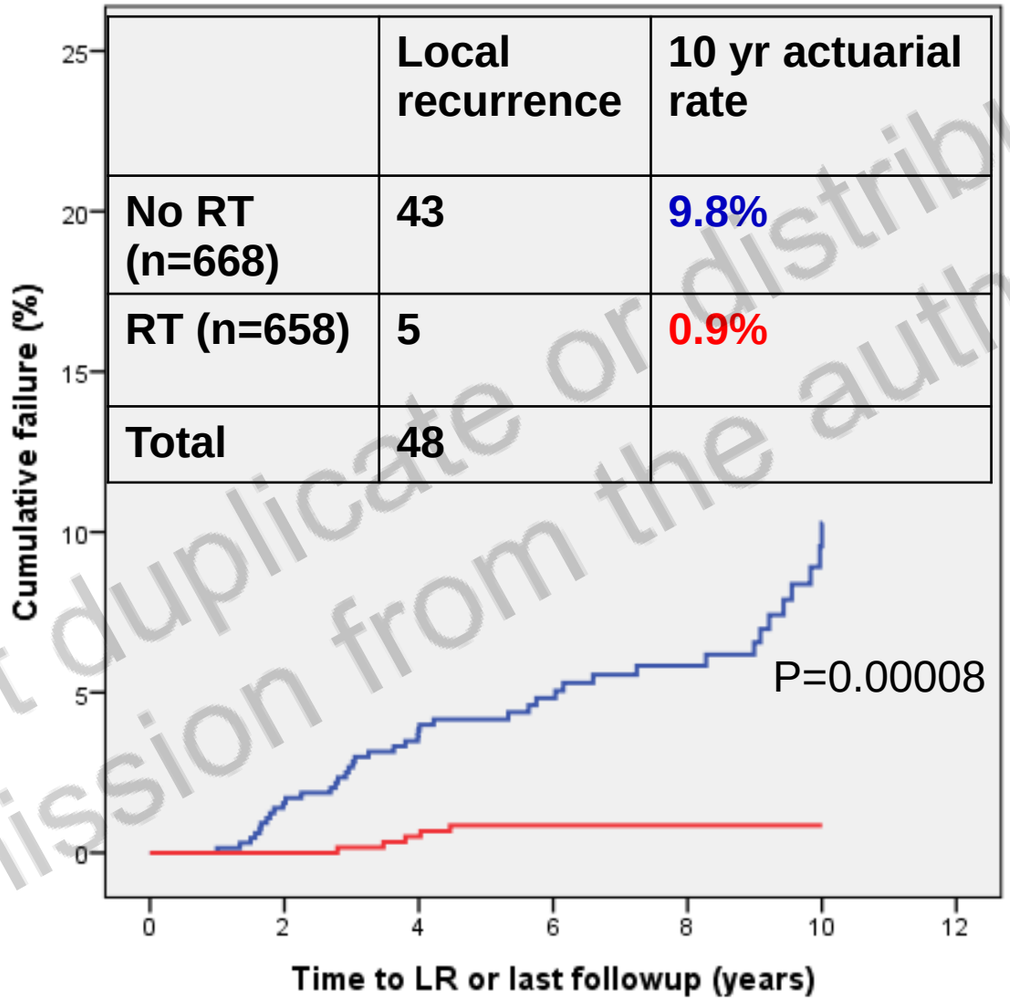
PRIME I QoL

EORTC QLQ-C30 Scale



PRIME 2 Local control at 10 years

	Local recurrence	10 yr actuarial rate
No RT (n=668)	43	9.8%
RT (n=658)	5	0.9%
Total	48	



Omission of RT post BCS:guidelines

NICE guidance (2018)

‘Consider omitting radiotherapy for women who:
have had breast-conserving surgery for invasive breast cancer with clear margins **and**
have a very low absolute risk of local recurrence (defined as women aged 65 and over with tumours that are T1N0, ER-positive, HER2-negative and grade 1 to 2) **and** are willing to take adjuvant endocrine therapy for a minimum of 5 years

Quality Indicators in breast cancer care(EUSOMA)

‘ Older patients (age >70) with small tumours who do receive adjuvant endocrine therapy may be treated without RT without a subsequent reduction in OS. **Before extending this to a broader group of patients, an update with longer follow up of the pubiished studies should be performed and a comparison between the respective benefits and side effects of of postoperative RT and adjuvant endocrine therapy are warranted.**
(Biganzoli et al, EJC 2017;86:59-81)

NCCN version 5.2020

‘Breast irradiation may be omitted in patients =/> 70 y of age with ER-positive, T1 tumours who receive adjuvant endocrine therapy’ … **the Prime II study results were also considered. The panel believed the data need further maturation before recommending omission of RT in patients aged =/>65 yr** (VanderWalde et al IJRBOP 2017;98:721-725)

Trials of breast hypofractionation

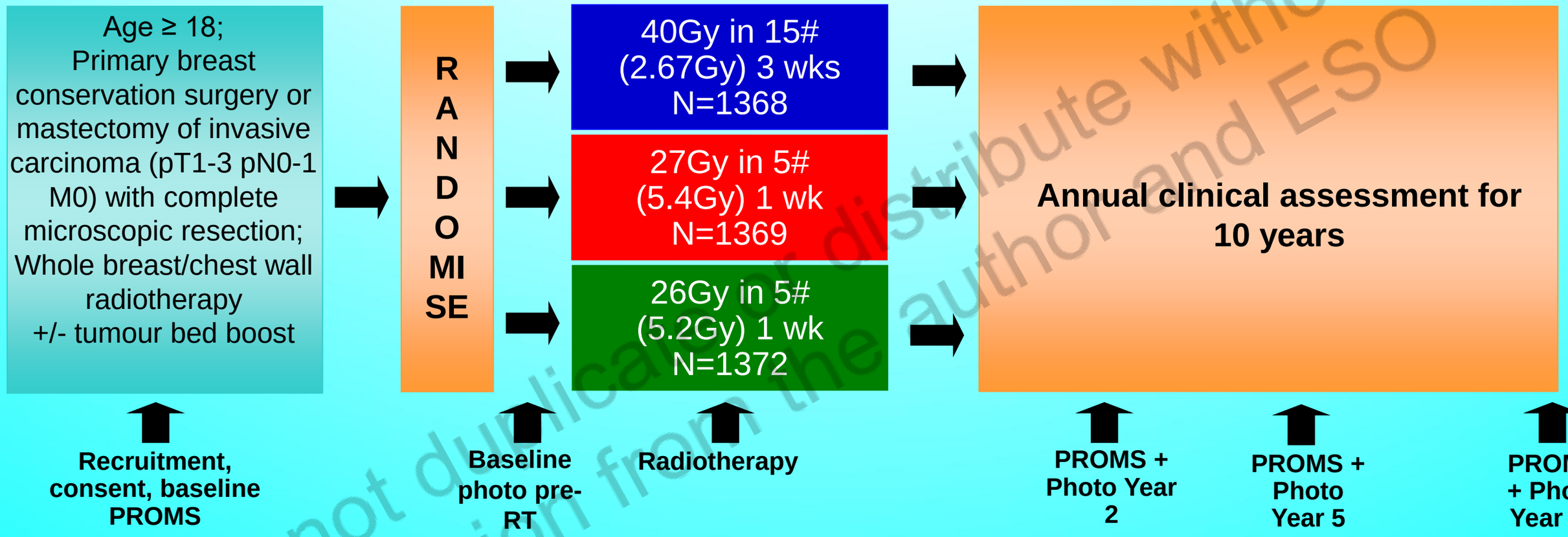
Table 2 Baseline characteristics of randomized trials of hypofractionated radiotherapy for breast cancer (HF-WBRT)

Variable	START trial A (85)	START trial B (87)	Canadian study (88)
Patients, n	2,236	2,215	1,234
Study type	Multicentric, randomized	Multicentric, randomized	Multicentric, randomized
Age, years			
≤60	1,358 (60.7%)	1,331 (60%)	646 (52.3%)
>60	878 (39.3%)	884 (40%)	588 (47.7%)
Histological type			
Invasive ductal	1,750 (78.3%)	1,708 (77.1%)	
Invasive lobular	266 (11.9%)	254 (11.5%)	Invasive carcinoma
Other	220 (9.9%)	453 (11.4%)	
Tumor size (cm)			
≤2	1,138 (50.9%)	1,412 (63.8%)	994 (80.6%)
>2	1,085 (48.6%)	795 (35.8 %)	240 (19.4%)
Not known	13 (0.5%)	8 (0.4%)	
Primary surgery			
Breast-conserving (BCS)	1,900 (85.0%)	2,038 (92.0%)	BCS alone
Mastectomy	336 (15.0%)	177 (8.0%)	
Randomization	50 Gy, 25 fx[‡]/41.6 Gy, 13 fx/39 Gy, 13 fx	50 Gy, 25 fx/40 Gy, 15 fx	50 Gy, 25 fx/42.5 Gy, 16 fx
N (randomization)	749/750/737	1,105/1,110	612/612
Follow up	5 and 10 years	5 and 10 years	10 years
Local relapse (estimated % with event by 10 yrs)	7.4%/6.3%*/8.8%**	5.5%/4.3%***	6.7%/6.2%****
Normal tissue effects (breast induration, telangiectasia, edema)	Significantly less common in the 39 Gy group *vs.* the 50 Gy group	Significantly less common in the 40 Gy group *vs.* the 50 Gy group	71.3%/69.8%[ɨ]

[‡]Fractions; *HR 0.91, P=0.65; **HR 1.18, P=0.41; ***HR 0.77, P=0.21; ****absolute difference, 0.5 percentage points, 95% CI, −2.5 to 3.5; [ɨ]good or excellent cosmetic outcomes (absolute difference, 1.5 percentage points; 95% CI, −6.9 to 9.8).

FAST-Forward

CI – Prof John Yarnold; Sponsor – ICR, Funder – NIHR HTA



Primary Endpoint: ipsilateral local tumour control

Secondary Endpoints: early and late adverse effects in normal tissues, patient reported outcome measures of late adverse effects and quality of life, health economics, relapse free survival, disease free survival, time to distant metastases and overall survival.

Recruitment: 4110 in main trial, 1798 in PROMS, 1737 in photographs, 3878 consented to donate a single blood sample, 4077 consented to donate their tissue.

Representation of older patients in randomised trials of hypofractionation				
Trial	**By age group**			
Whelan et al (2002)		42.5 Gy in 16 fr n=622 (%)	50 Gy in 25 fr n=612 (%)	
	<50	157 (25)	%)	
	50 - 59	186 (30)	155 (25	
	60 - 69	181 (29)	200 (33)	
	> 70	98 (16)	109 (18)	
Start A n=2236 Start Trialist Group 2008a		50 Gy in 25 fr n= 749 (%)	41.6 Gy in 13 fr n=750 (%)	39 Gy in 13 fr n=737 (%)
	20 - 29	5 (0.7)	4 (0.5)	3 (0.4)
	30 - 39	38 (5.1)	40 (5.3)	38 (5.2)
	40 - 49	116 (15.5)	136 (18.1)	129 (13.5)
	50 - 59	280 (37.4)	283 (37.7)	256 (38.8)
	60 - 69	215 (28.7)	192 (25.6)	194 (26.3)
	70 - 79	87 (11.6)	85 (11.3)	78 (10.6)
	> 80	8 (1.1)	10 (1.3)	9 (1.2)
Start B n=2215 Start Trialist Group 2008 b		50 Gy in 25 fr n=1105 (%)	40 Gy in 15 fr n= 1110 (%)	
	20 -29	7 (0.6)	0 (0%)	
	30 - 39	62 (5.6)	39 (3.5)	
	40 - 49	179 (16.2)	179 (15.3)	
	50 - 59	427 (38.6)	447 (40.3)	
	60 - 69	304 (17.5)	327 (29.5)	
	70 - 79	117 (10.6)	119 (10.7)	
	> 80	9 (0.8)	8 (0.7)	

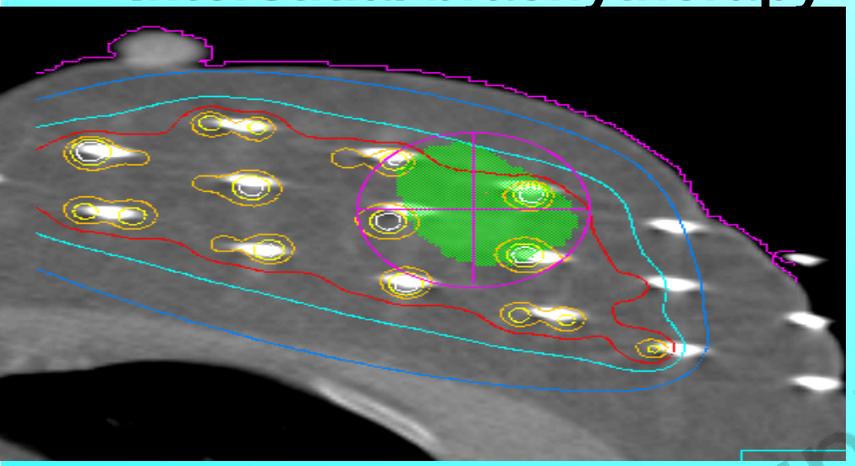
Table by Prof Ian Kunkler

Representation of older patients in randomised trials of hypofractionation				
FAST Brunt et al 2020 (a)		50 Gy in 25 Fr n=302 (%)	30 Gy in 5 fr n=308 (%)	28.5 Gy in 5 fr n=305 (%)
	50 - 59	112 (37.1)	112 (36.4)	110 (36.1)
	60 - 69	143 (47.4)	145 (47.1)	153 (50.2)
	70 - 79	44 (14.6)	42 (13.6)	39 (12.5)
	> 80	3 (1.0)	9 (2.4)	3 (1.0)
FAST FORWARD Brunt et al (2020) (b)		40 Gy in 15 fr n=1361 (%)	27 Gy ub 5 fr n=1367 (%)	26 Gy in 5 fr n=1368
	<40	12 (1.9)	16 (1.2)	28 (2.0)
	40 - 49	186 (13.7)	173 (12.7)	189 (13.8)
	50 - 59	440 (32.3)	423 (30.9)	414 (30.3)
	60 - 69	506 (37.2)	511 (37.4)	524 (38.3)
	70 - 79	175 (12.9)	197 (14.4)	172 (12.6)
	> 80	42 (3.1)	47 (3.4)	41 (3.0)
Offersen et al (2020)		50 Gy in 25 fr n= 937 (%)	40 Gy in 15 fr n=917 (%)	
	41 - 49	101 (11)	98 (11)	
	50 59	389 (42)	383 (42)	
	60 - 69	349 (37)	351 938)	
	70 - 83	98 (10)	85 (9)	

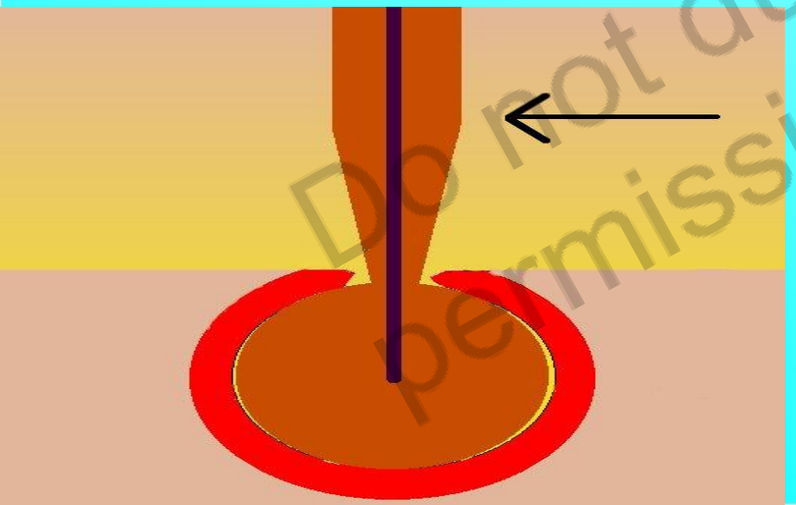
Table cont. by Prof Ian Kunkler

Types of partial breast irradiation in RCTs

Interstitial brachytherapy

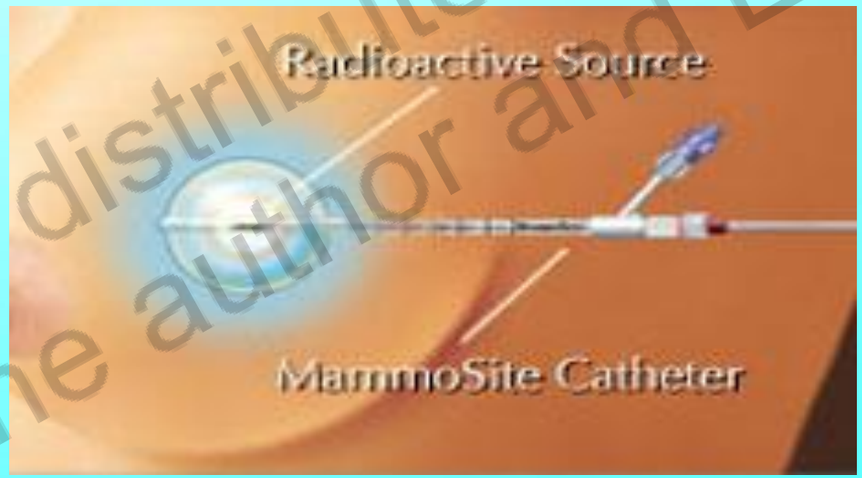


32 Gy in 8fr

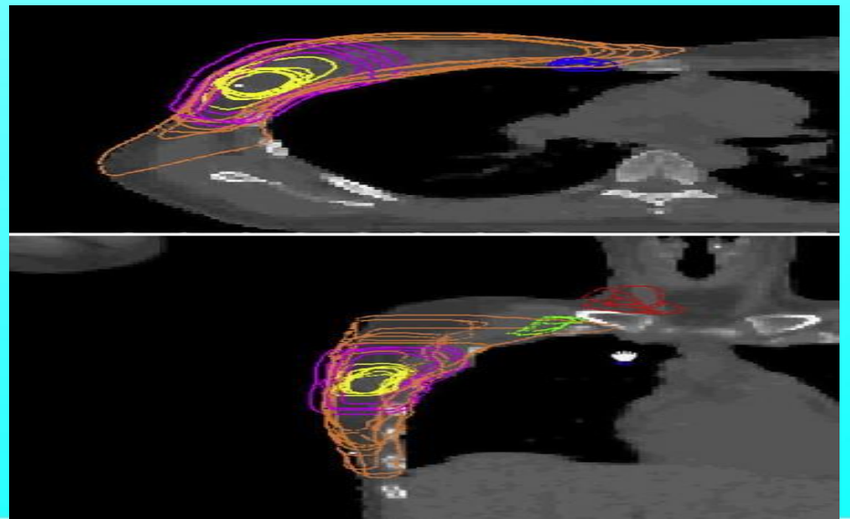


20-21 Gy in 1 fr

Intracavitary brachytherapy

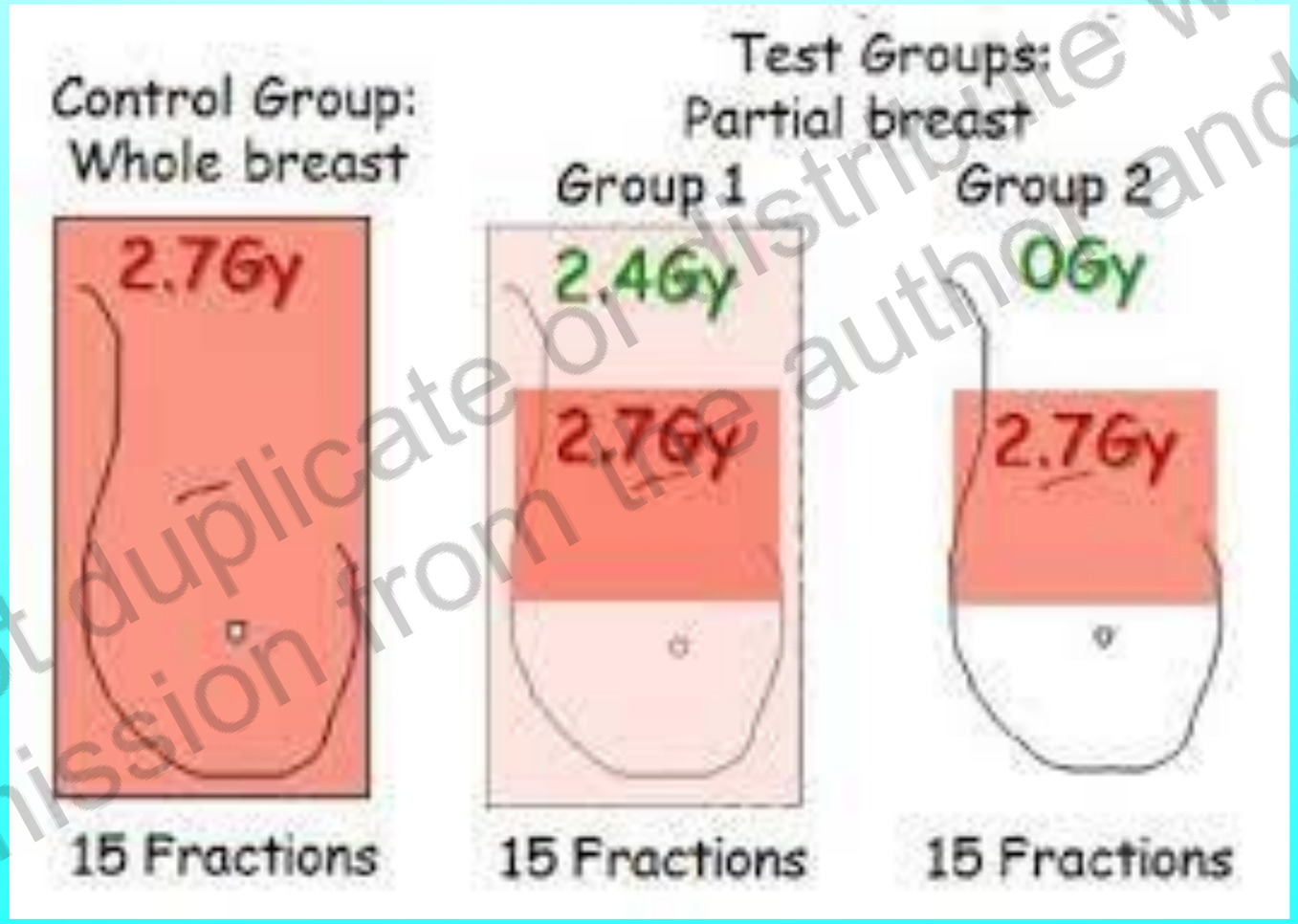


34 Gy in 10fr



38 Gy in 10 fr

IMPORT –Low trial
(Coles et al Lancet 2017;90:1048-60)



Randomised trials of partial breast irradiation

Table 3 Randomized trials of partial breast irradiation (PBI) after BCS for breast cancer

Variable	IMPORT LOW (103)	Barcelona (104)	GEC-ESTRO (112)	TARGIT-A (105)	ELIOT (106)	Hungary (109)	University of Florence (111)	RAPID (111)
Patients, n	2,016	102	1,184	3,451	1,305	258	520	2,135
Study type	Multicentric, randomized	Multicentric, randomized	Multicentric, randomized	Multicentric, randomized	Single center, randomized	Multicentric, randomized	Multicentric, randomized	Multicentric, randomized
Randomization	WBRT/HF-WBRT/PBI	PBI/WBRT	PBI/WBRT	IORT/WBRT	IORT/WBRT	PBI/WBRT	PBI/WBRT	PBI/WBRT
N	674/673/669	51/51	633/551	1,721/1,730	651/654	128/130	260/260	1,070/1,065
Dose-fractionation PBI arm	40 Gy/15 fx	37.5 Gy/10 fx BID	32 Gy/8 fx, 30.3 Gy/7 fx (HDR) BID; 50 Gy (PDR)	20 Gy SD to the surface of the tumor bed	21 Gy SD prescribed to the 90% depth	36.4 Gy/7 fx (HDR); 50 Gy/25 fx (electron)	30 Gy/5 fx (QOD)	38.5 Gy/10 fx BID
Technique	IMRT	3D-CRT	HDR	IORT	IORT (electron)	HDr/electron	IMRT	3D-CRT
Age distribution								
≤60	Mean age: WBRT: 63 y	Mean age: WBRT: 70.1 y; PBI: 67.1 y	536 Pt (45.3%)	1,347 Pt (39.1%)	640 Pt (49.1%)	152 Pt (58.9%)	223 Pt (42.8%)	≤50: 257 Pt (12%)
>60	Reduced WBRT: 63 y; PBI: 62 y		648 Pt (54.7%)	2,104 Pt (60.9%)	665 Pt (51%)	106 Pt (41.1%)	297 Pt (57.1%)	>50: 1,878 Pt (88%)
Histology	IDC	IDC	IC/DCIS	IDC	IDC/ILC	IDC	IC/DCIS	IDC/DCIS
Tumor size (cm)	≤3	≤3	≤3	≤3.5	≤2.5	≤2	≤2.5	≤3
Nodal status	Negative/pN1	Negative	Negative/pN1mi/ pN1a (by ALND)	N0, N1	Negative. If positive: WBRT	N0, N1mi	Negative, pN1	Negative
Follow up	5-year cumulative incidence	5 years	5 years	5 years	5 years	5 years	5 years	5 and 8 year cumulative rates
LR (%)	1.1/0.2/0.8	0	1.44/0.92	3.3/1.3	4.4/0.4	4.7/3.4	1.5/1.9	5 y: 2.3, 8 y: 3.0/5 y: 1.7, 8 y: 2.8
OS (%)	No significant differences	No significant differences	97.3/95.5. No significant differences	No differences, but significantly fewer non-breast-cancer deaths with TARGIT	96.8/96.9. No significant differences	94.6/91.8. No significant differences	99.4/96.6. No significant differences	–

BCS, breast conserving surgery; ALND, axillary lymph node dissection; IDC, invasive ductal carcinoma; IC, invasive carcinoma (any type); DCIS, ductal carcinoma *in situ*; GEC-ESTRO, Groupe Européen de Curiethérapie and European Society for Radiotherapy and Oncology; ASBS, American Society of Breast Surgeons; ASTRO, American Society for Therapeutic Radiology and Oncology; ABS, American Brachytherapy; BID, twice a day (bis in die); HDR, high dose rate interstitial brachytherapy; PDR, pulsed dose rate brachytherapy; SD, single-dose; QOD, every other day (quaque altera die); Pt, patients; WBRT, whole breast radiotherapy; HF-WBRT, hypofractionated whole breast radiotherapy.

Recommendations for ABPI

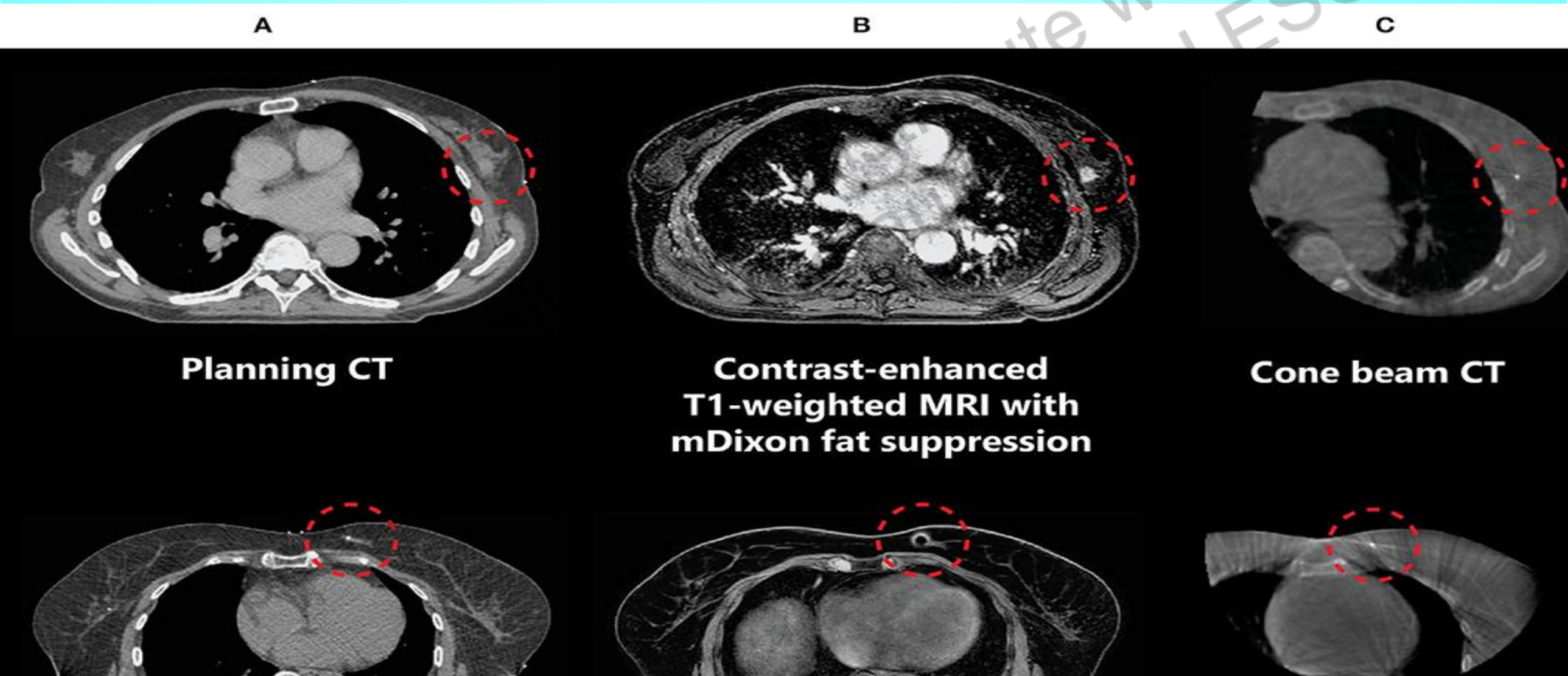
Table 1 Recommendations on patient selection for accelerated partial breast irradiation (APBI) from American Society for Radiation Oncology (ASTRO), Groupe Européen de Curiethérapie - European Society for Radiotherapy and Oncology (GEC-ESTRO), and American Brachytherapy Society (ABS)

Variables	ASTRO, Smith 2009 (5)	GEC-ESTRO, Polgár 2010 (6)	ABS, Shah 2013 (7)
Age (years)	≥60	≥50	≥50
BRCA mutation	Not present	–	–
Tumor size	≤2 cm	≤3 cm	≤3 cm
Nodal status	pN0 (SN or ALND)	pN0 (SN or ALND)	pN0 (SN or ALND)
Resection margin	≥2 mm	≥2 mm	Negative
Tumor grade	Any	Any	–
Lymphovascular space invasion	Not present	Not present	Not present
Estrogen receptors	Positive	Positive	Positive/negative
Multicentricity	Unicentric	Unicentric	–
Multifokality	Unifocal	Unifocal	–
Histology	Invasive ductal	Invasive ductal	Any invasive, ductal *in situ*
Extensive intraducal component	Not present	Not present	–
Neoadjuvant therapy	Not allowed	Not allowed	–

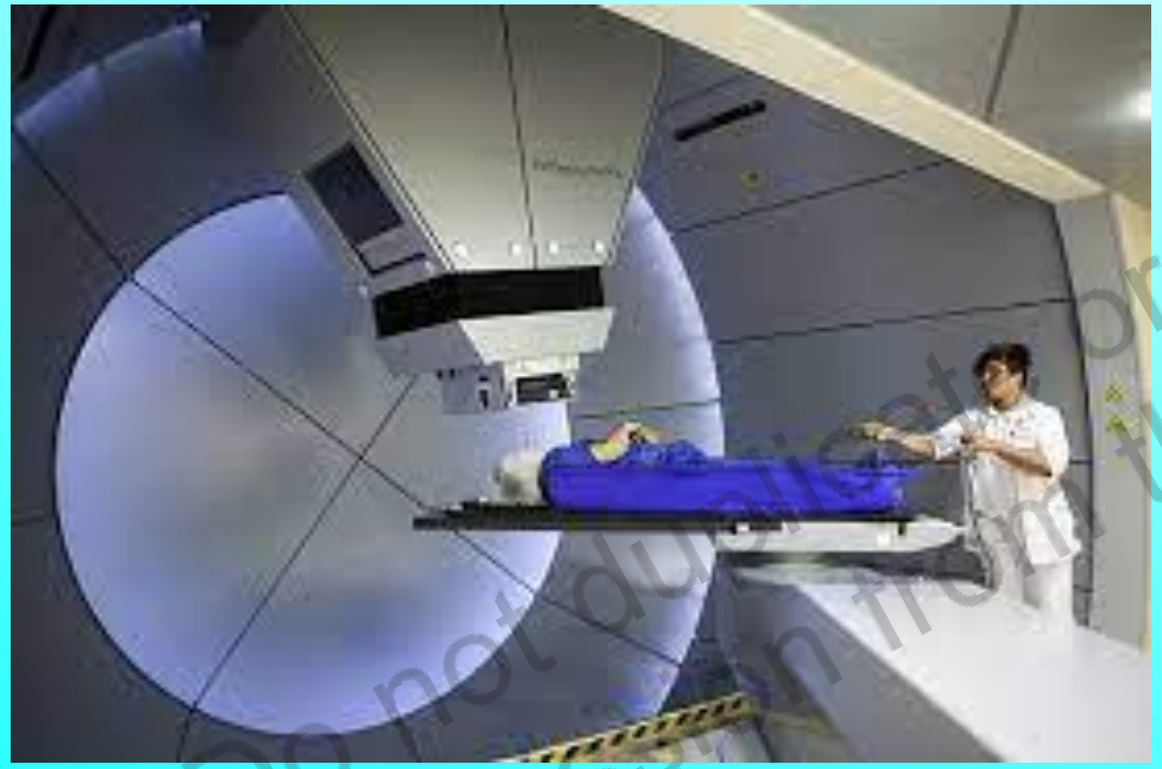
Sirák I et al. Transl Cancer Res 2020;9(Suppl 1)

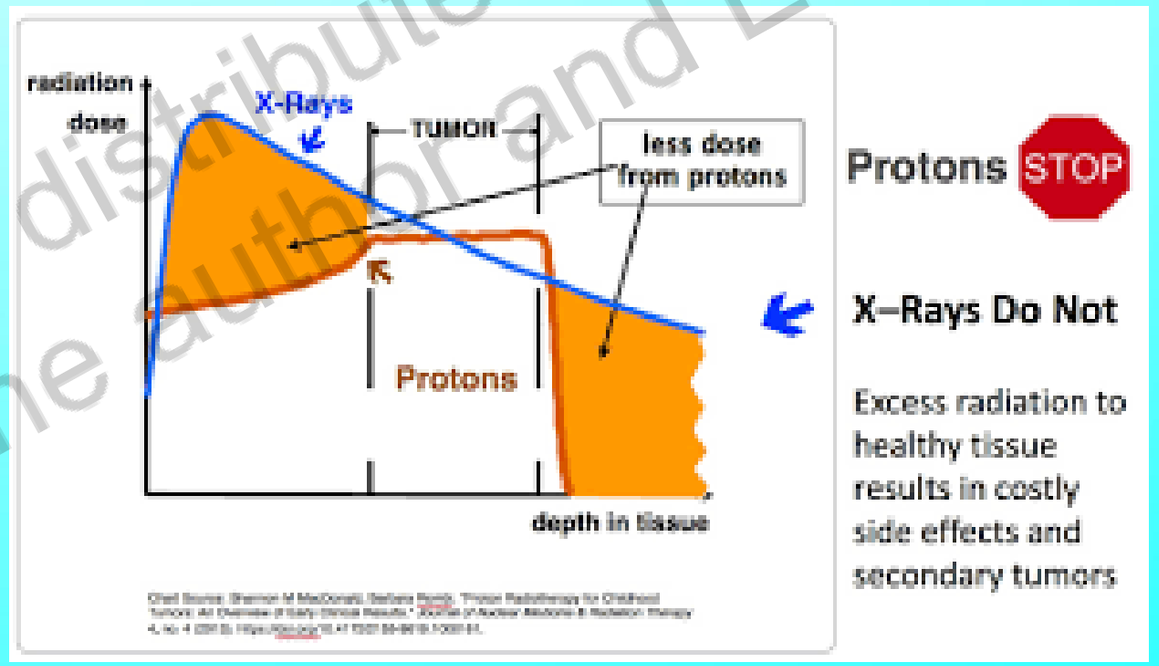
Future directions

Imaging breast cancer on planning CT, MRI and cone beam CT (Koerkamp et al, Front Oncol 2020;10:1-13)



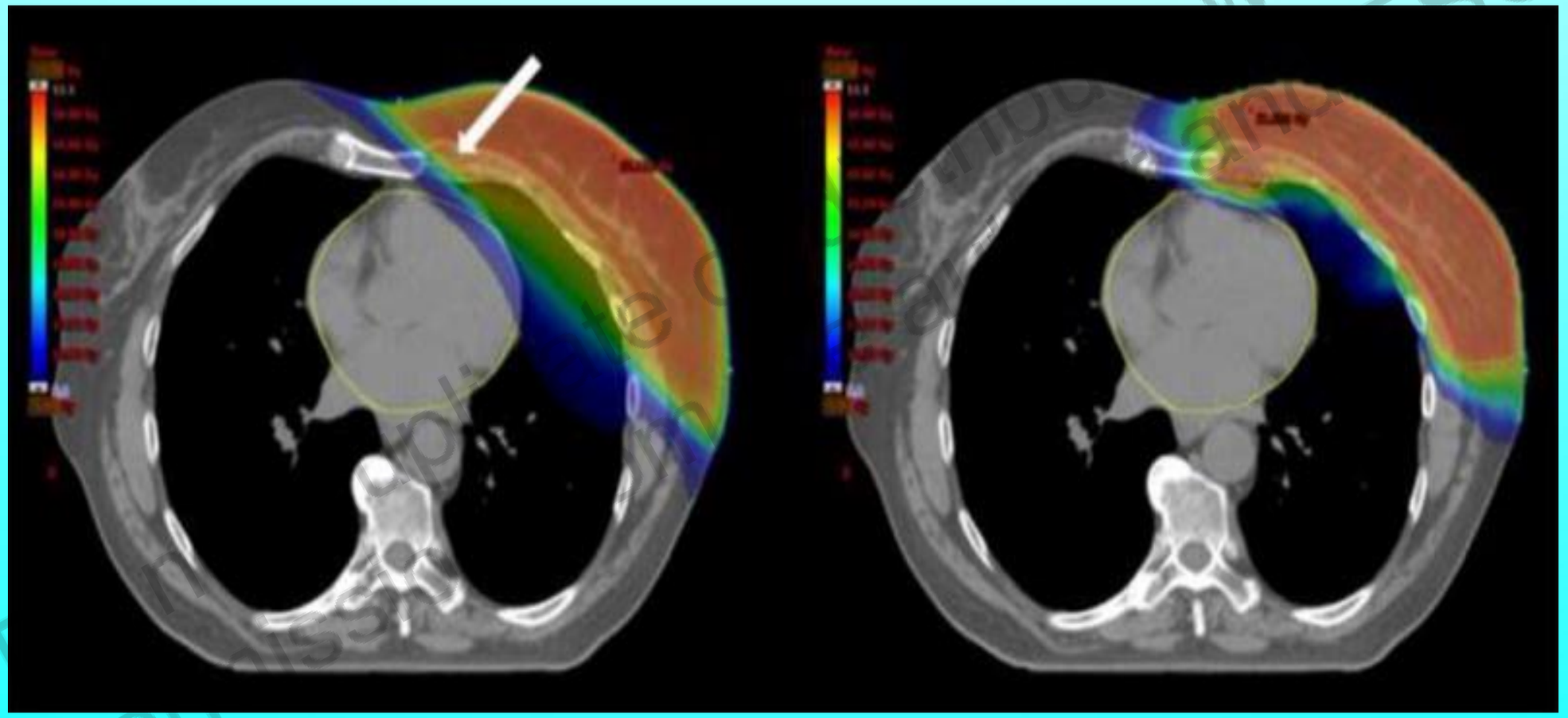
Proton therapy





Dose distribution: photons and protons

(Stick et al IJRBOP 2017;97:754-761)



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Conclusions

- There is a need for geriatric assessment to be integrated into MDTs for older patients who are candidates for RT after BCS
- There are no validated tools predicting radiation toxicity
- Breath hold techniques and potential for protons to reduce cardiotoxicity
- Omission of postop RT an option for, ER positive, =/>65 yr, pT1-2 (up to 3cm), pN0 with at least 5 years of adjuvant endocrine therapy
- Hypofractionation in 15/16 fr. and more recently in 5 fr. well validated in recent trials
- Partial breast irradiation by a variety of techniques can maintain good local control with less normal tissue toxicity
- MRI based neoadjuvant ABPI and proton therapy under evaluation

BREAST CANCER IN THE ELDERLY

ONLINE COURSE

Can we adapt the standard according to patient's health status?

Medical Oncology in early breast cancer

Laura Biganzoli

Medical Oncology Department

Breast Centre

Hospital of Prato

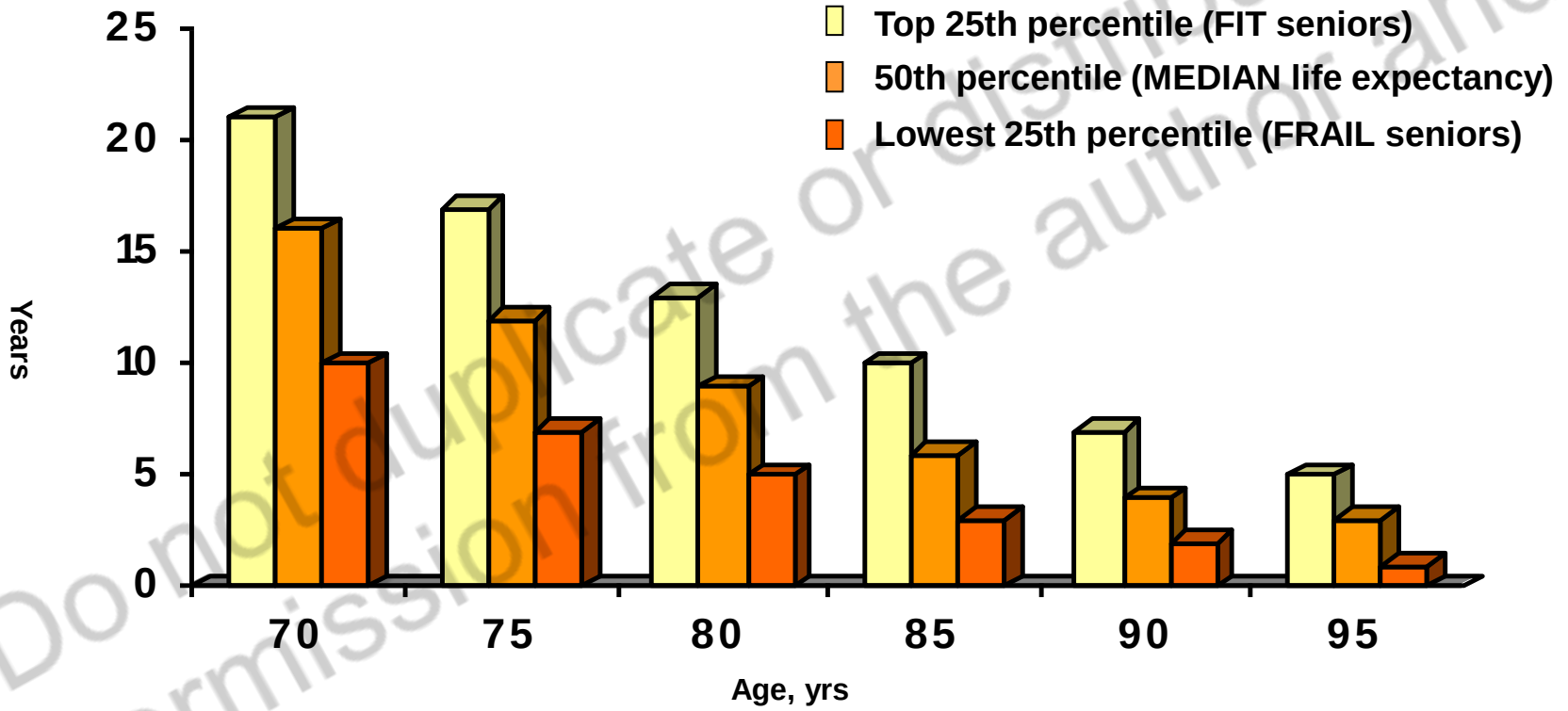
Italy

Disclosure Information

- **Personal financial interests** (Honoraria, consultancy or advisory role):
AstraZeneca, Daiichi-Sankyo, Eisai, Genomic Health, Lilly, Novartis, Pfizer, Pierre Fabre

- **Institutional financial interests**: Celgene, Genomic Health, Novartis

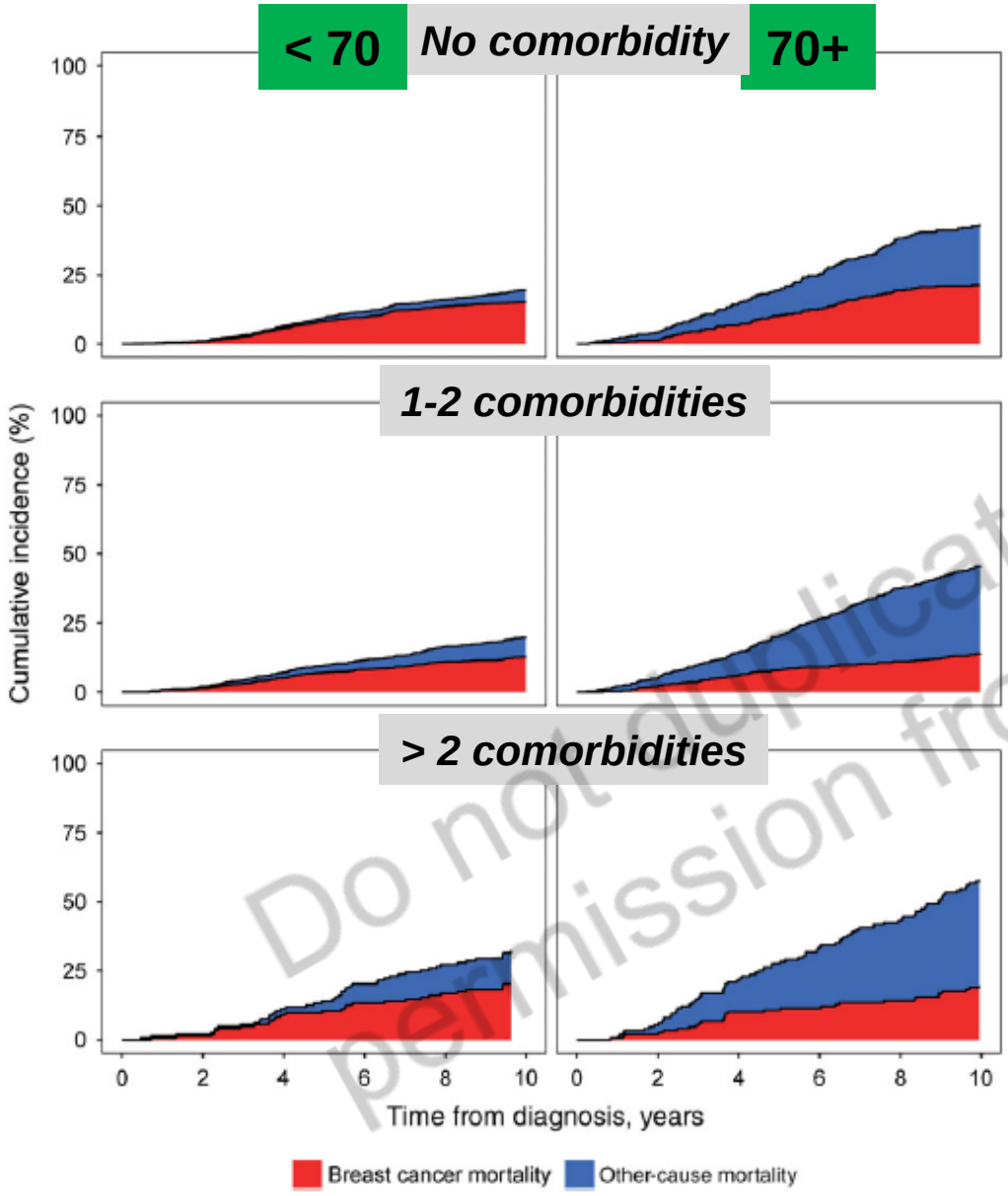
Life expectancy in senior adults: a large variability reflecting health status variability



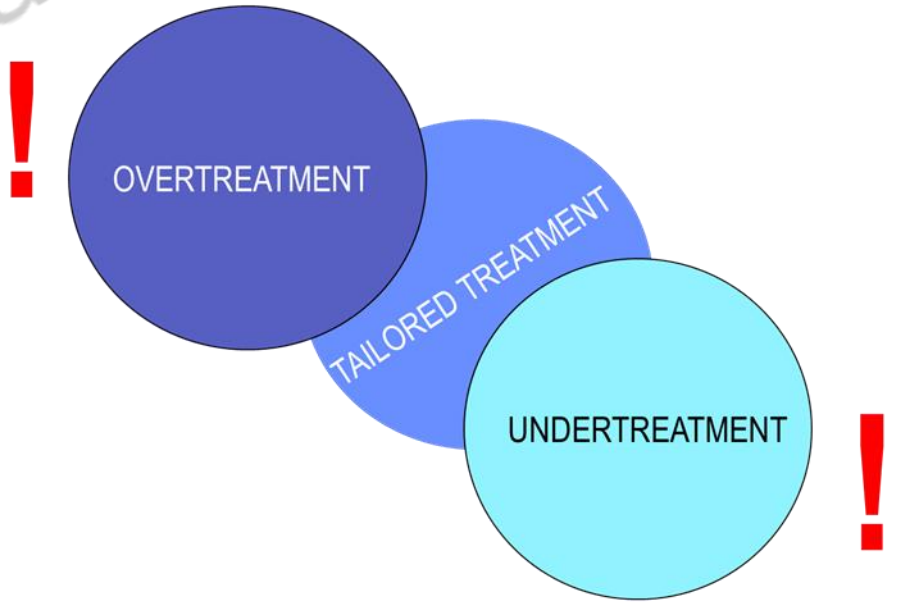
Life expectancy for elderly women based on heath status

Walters et al. JAMA 2001

Competing risks for mortality



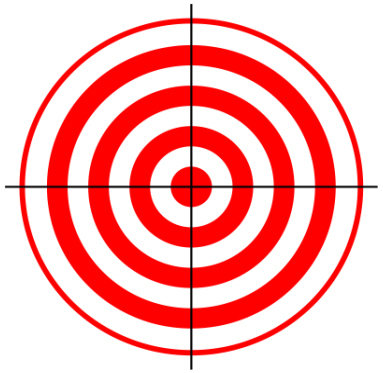
≥70 yr & no comorbidity (33%)
→ higher BC mortality
10-year
22.2% (95% CI 17.5–26.9) vs 15.6% (95% CI 13.6–17.7)
sHR 1.49 (95% CI 1.12–1.97)
p = .005



Derks et al. The Oncologist 2019

Neo/Adjuvant therapy

TARGET the TUMOR



- Stage
- Biology

TARGET the PATIENT

- Physiological age
- Estimated life expectancy
- Treatment tolerance
- Patient preference/expectation
- Potential barriers to treatment

Instruments

-Screening/Geriatric assessment
- Prognostic tools (https://eprognosis.ucsf.edu)
- Predictors of breast cancer survival (PREDICT)
- Chemotherapy toxicity calculators (CARG, CRASH)

Potential risks vs. expected absolute benefits

→ **Develop an integrated and individualized plan for patients**
→ **Identify non-oncologic problems that may be amenable to intervention**

Focus

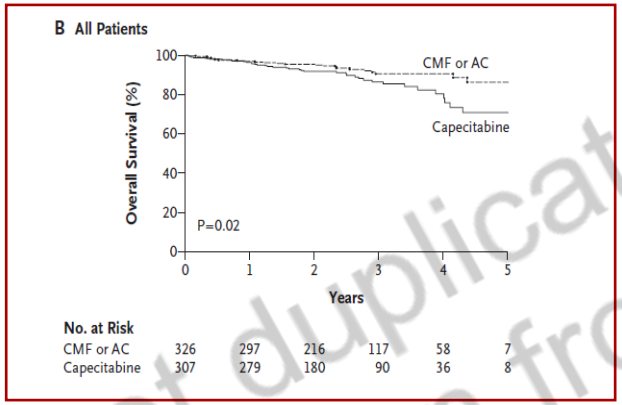
- Adjuvant chemotherapy
- Adjuvant strategy in patients with HER2+ tumors
- Neoadjuvant therapy in TN & HER2+ tumors

Prospective trials specifically conducted in older patients

CALGB 49907

633 women aged ≥65 stage I-IIIB BC

AC/CMF vs capecitabine (X)



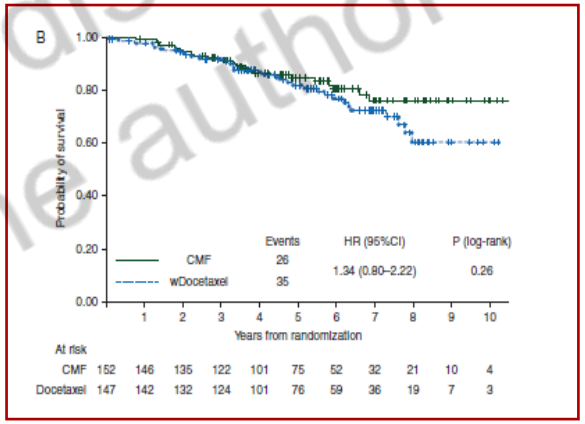
- **10-year BCSS advantage with polychemotherapy**

Muss et al. N Engl J Med 2009

ELDA trial

302 women aged 65-79 average-high risk of relapse

CMF vs weekly docetaxel(D)



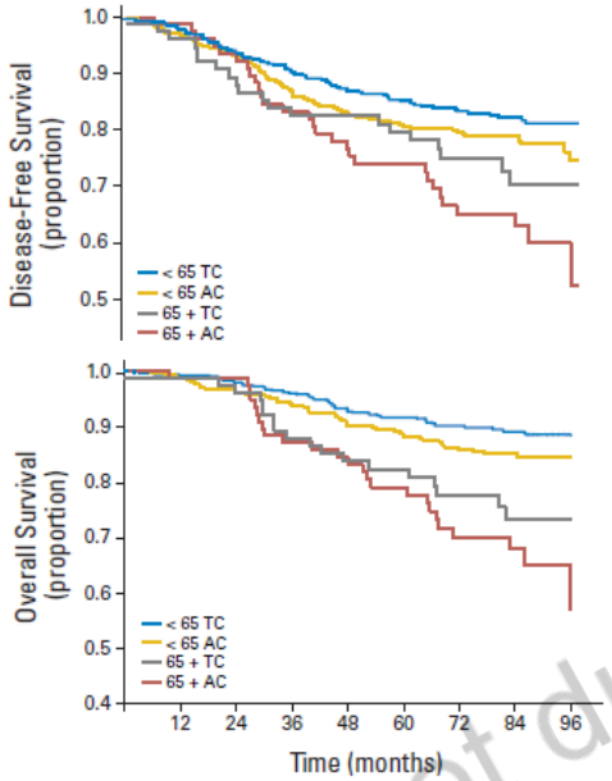
- **Weekly D worsens QoL & toxicity**

Perrone et al. Ann Oncol 2015

Elderly fit patients should be treated with standard regimens

A→ T regimens

US Oncology Research Trial 9735

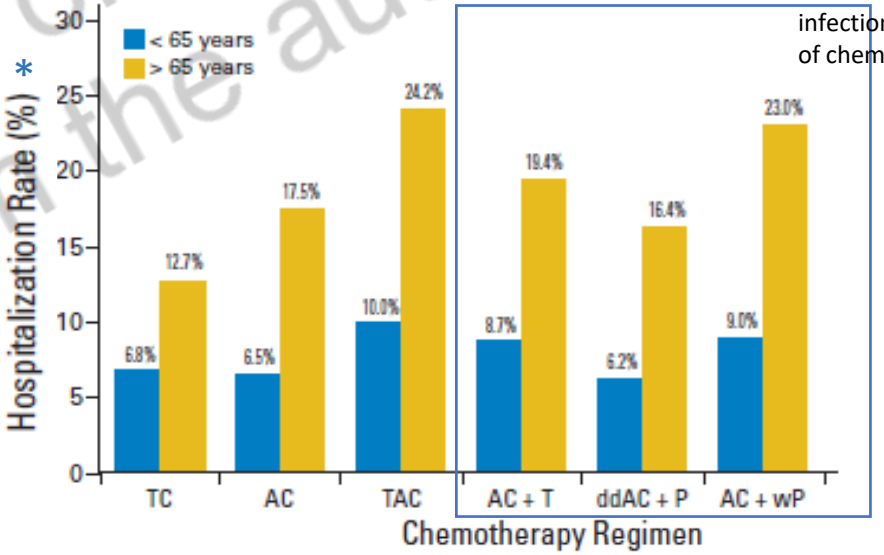


TC superior to AC irrespective of age

Jones et al. J Clin Oncol 2009

- Not prospectively evaluated in older patients
- Retrospective per-age subgroup analysis from RCT (FIT highly selected pts): ↑hematological toxicity & treatment related deaths and more dose delays, reductions, hospitalizations, and treatment discontinuations in the elderly
- Registry data

Muss et al. J Clin Oncol 2007, Loibl et al, Breast Cancer Res 2008



*chemotherapy-related reasons (neutropenia, fever, infection, thrombocytopenia, anemia, adverse effects of chemotherapy, dehydration, delirium)

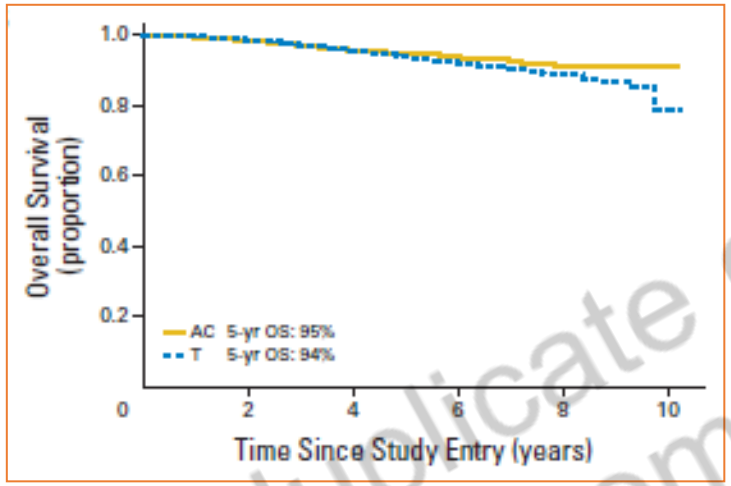
The Charlson comorbidity score was independently associated with hospitalization

For selected high-risk healthy elderly patients

Barcenas et al. J Clin Oncol 2014

Comparison of Doxorubicin and Cyclophosphamide Versus Single-Agent Paclitaxel As Adjuvant Therapy for Breast Cancer in Women With 0 to 3 Positive Axillary Nodes: CALGB 40101 (Alliance)

Single agent paclitaxel (P) vs AC



1% absolute difference in OS

- The trial did not show noninferiority of P to AC
- P was less toxic than AC

Shulman et al. J Clin Oncol 2014

Weekly paclitaxel may be considered in high-risk pts who are considered unfit for poly-chemotherapy

Adjuvant trastuzumab

- Adjuvant trastuzumab reduces mortality by a third and relapse by 40% . However, of more than 20,000 women included in trials of adjuvant trastuzumab, only about 1,000 were 60 years or older

- Adjuvant therapy in older patients with HER2+ EBC should take into account risk of relapse, life expectancy (assessed through geriatric assessment), expected tolerability (including cardiac), and patient preference

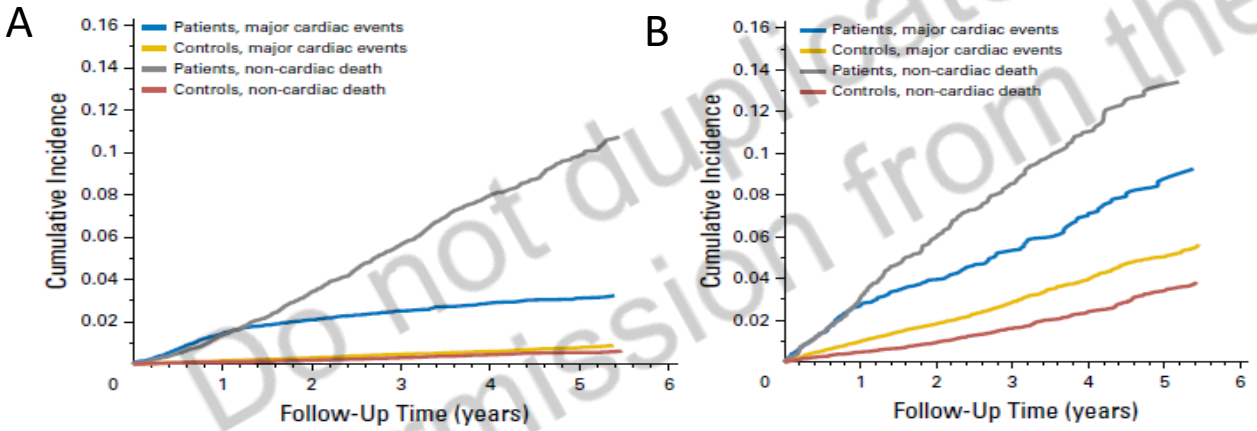
- In EBC, cardiotoxicity occurred in 2.90% of patients treated with taxanes and anthracyclines compared to 0.92% in patients treated with taxanes without anthracyclines. The occurrence of cardiotoxicity varied according to age, increasing from 2.31% in individuals <50 years, to 3.46% in those 50-59 years, to 4.91% in those >60 years of age.

Brain E , J Geriatric Oncology 2019, Mantarro S Internal Med Emerg 2016

Breast Cancer Therapy–Related Cardiac Dysfunction in Adult Women Treated in Routine Clinical Practice: A Population-Based Cohort Study

N = 18,540 early BC women treated with chemotherapy (A-based or other); trastuzumab (without A-based chemotherapy or sequential to A-based chemotherapy) N=3891 ≥65

- Patients aged ≥ 65 years had a higher cumulative incidence of major cardiac events compared with pts <65; however, there was no significant interaction between age and treatment on the hazard of major cardiac events ie, same proportional risk between younger and older pts



Cumulative incidence of major cardiac events stratified by age (A <65 years ;B ≥ 65 years) compared with matched control population

HRs for major cardiac events (A and T-free regimens vs A→T and vs T without A) 3.96 and 1.76

A, anthracycline; T, trastuzumab

Thavendiranathan et al. J Clin Oncol 2016

Chemotherapy and anti-HER2 therapy in HER2+ patients

➢ De-escalation on the chemotherapy backbone

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

- Preferred chemotherapy backbone: four cycles of TC or weekly paclitaxel for 12 (avoiding cardiac toxicity of anthracyclines and duration of chemotherapy beyond 3 months)
- A sequential regimen of anthracyclines and taxanes with trastuzumab is appropriate only in a very selected group of fit, healthy older patients

HER2-targeted treatment for older patients with breast cancer: An expert position paper from the International Society of Geriatric Oncology

Patients unfit for polychemotherapy

- In frail older patients and/or those with low-risk tumors, weekly paclitaxel is the preferred regimen to combine with trastuzumab

Biganzoli et al. Lancet Oncol 2021; Brain et al. JGO 2019

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

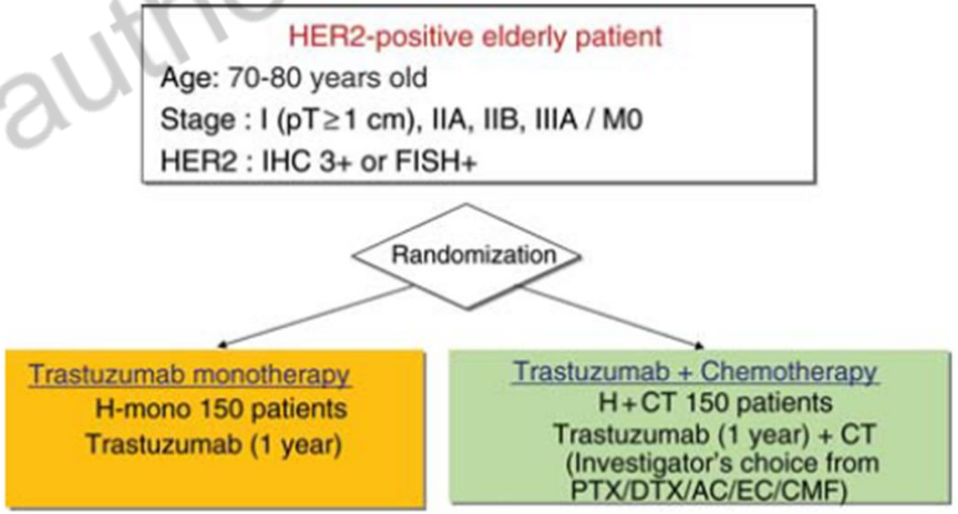
- Pertuzumab can be added only in high risk and fit patients, but diarrhea can be a debilitating side effect in older individuals
- Extended adjuvant therapy with neratinib is probably not an appropriate option for older patients because of potential risk of grade ≥3 diarrhea

Biganzoli et al. Lancet Oncol 2021

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

- The use of single-drug trastuzumab without chemotherapy, but with endocrine therapy if hormone sensitive, can be appropriate in susceptible and frail patients

Randomized Controlled Trial of Trastuzumab Wi[Check for updates] or Without Chemotherapy for HER2-Positive Early Breast Cancer in Older Patients



CONCLUSION The primary objective of noninferiority for trastuzumab monotherapy was not met. However, the observed loss of survival without chemotherapy was < 1 month at 3 years. Therefore, and in light of the lower toxicity and more favorable HRQoL profile, trastuzumab monotherapy can be considered an adjuvant therapy option for selected older patients.

Sawaki et al for the RESPECT study group. J Clin Oncol 2020

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

- Shorter courses of anti-HER2 therapy can be considered for older patients with small, node-negative tumors or in the context of cardiac problems

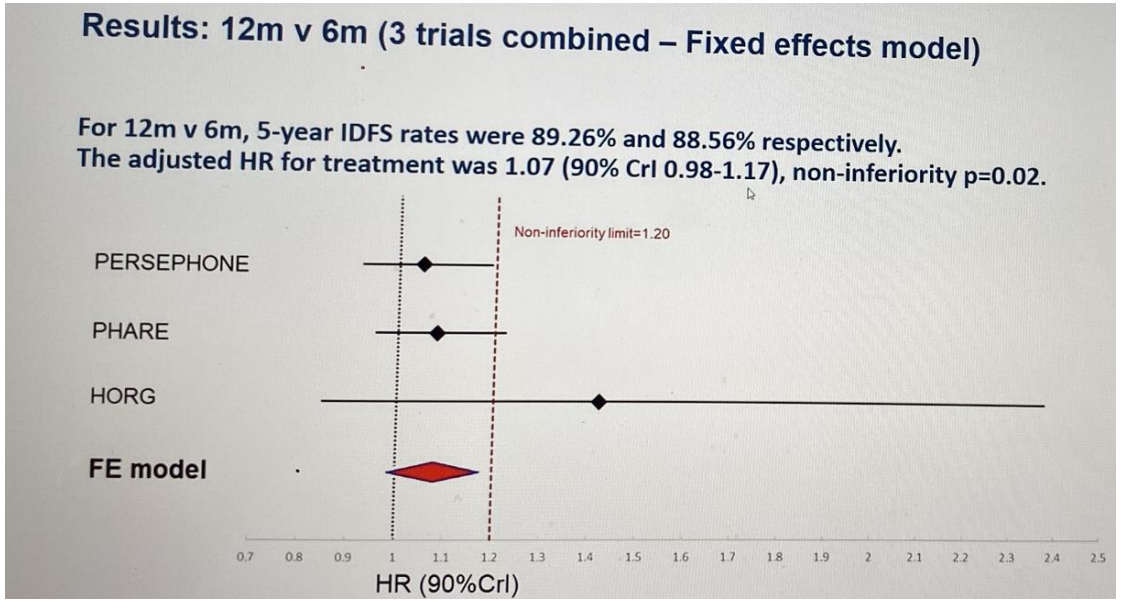
Meta-Analysis › Breast Cancer Res Treat. 2019 Jan;173(2):247-254.
doi: 10.1007/s10549-018-5001-x. Epub 2018 Oct 13.

One year versus a shorter duration of adjuvant trastuzumab for HER2-positive early breast cancer: a systematic review and meta-analysis

Alessandro Inno [1], Sandro Barni [2], Antonio Ghidini [3], Alberto Zaniboni [4], Fausto Petrelli [5]

Conclusions: One-year adjuvant trastuzumab is associated with better DFS and OS compared with shorter durations and should still be considered the standard duration. However, selected patients with low-risk HER2+ BC can most likely be spared from an excess of cardiac toxicity with a shorter course.

LBA11 - Individual patient data meta-analysis of 5 non-inferiority RCTs of reduced duration single agent adjuvant trastuzumab in the treatment of HER2 positive early breast cancer



Earl et al. ESMO 2021

Neoadjuvant systemic therapy & response-oriented adjuvant systemic therapy

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

- Carefully selected, fit, older patients should be considered for neoadjuvant systemic therapy similarly to younger women
- Less fit older patients are best served by upfront surgery, particularly if the breast cancer is already operable.

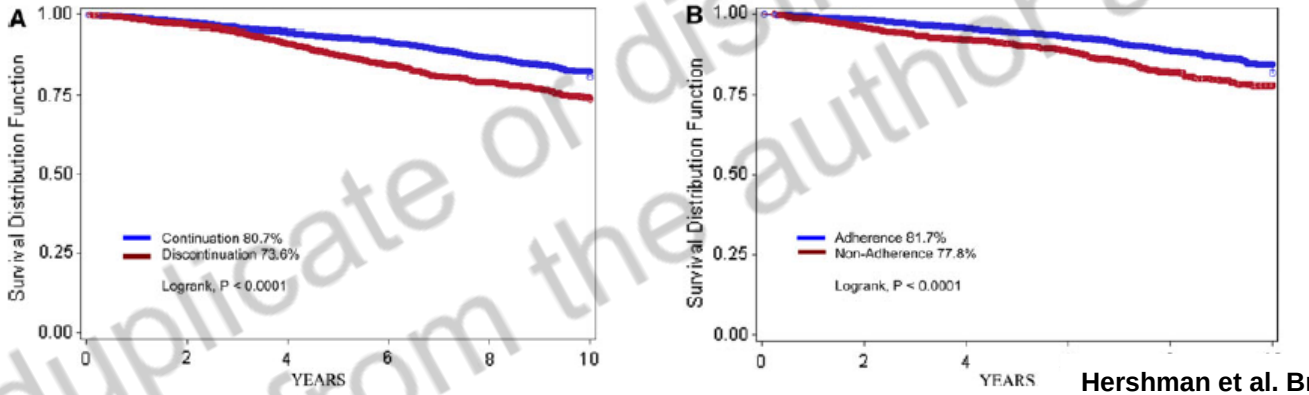
- Fit, older patients should be considered for adjuvant capecitabine in case of residual triple-negative disease
- Fit, older patients should be considered for adjuvant T-DM1 in case of residual HER2-positive disease

Biganzoli et al. Lancet Oncol 2021

Back up

En ɜpy

- As for younger postmenopausal pts; however, elderly patients are more vulnerable to toxicity and safety is important in choice of agent
- Omission is an option for patients with a very low-risk tumour (pT1aN0) or life-threatening comorbidities
- Compliance should be actively promoted



Hershman et al. Brest Cancer Res Treat 2011

Treatment Adherence and Its Impact on Disease-Free Survival in the Breast International Group 1-98 Trial of Tamoxifen and Letrozole, Alone and in Sequence

Table 2. Baseline Patient, Disease, Treatment Factors Related to Stopping Protocol-Assigned Treatment Early Because of Adverse Events

Factor	HR	95% Wald Confidence Limits		*P*
Age group, years				< .001
56-70 *v* ≤ 55	1.022	0.871	1.200	.78
70 or older *v* ≤ 55	1.478	1.196	1.826	< .001

Chirgwin et al. J Clin Oncol 2016

Potential barriers to oral therapy adherence in older patients

Factor	Barriers
Age-related	• Cognitive deficits • Visual/hearing impairment • Comorbidities ± geriatric syndromes • Disease severity and associated symptoms • Higher risk of toxicity • Polypharmacy • Regimen complexity • Personal health beliefs, including perceived need & effectiveness of treatment • Low health literacy • Poor socio-economic status or lack of social support or supervision • Poor physician-patient communication

Adapted from:

Sabate, E. Adherence to long-term therapies:Evidence for Action. World Health Organization, 2003.
Kardas, P. et al. Frontiers in Pharm. 2013;4(91).
Henriques M. et al. Journal of Clinical Nursing, 21, 3096–3105.

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

- **FIT:** good health status; may tolerate standard treatment as well as younger patients
- **VULNERABLE/PRE-FRAIL:** high risk of progressing to frailty with an entire range of reversibility; may require treatment adjustments or support for underlying comorbidities to improve treatment outcome
- **FRAIL:** increased risk of poor health outcomes along  educed resistance to stress; frequently suitable for supportive care alone

Biganzoli et al. Lancet Oncol 2021

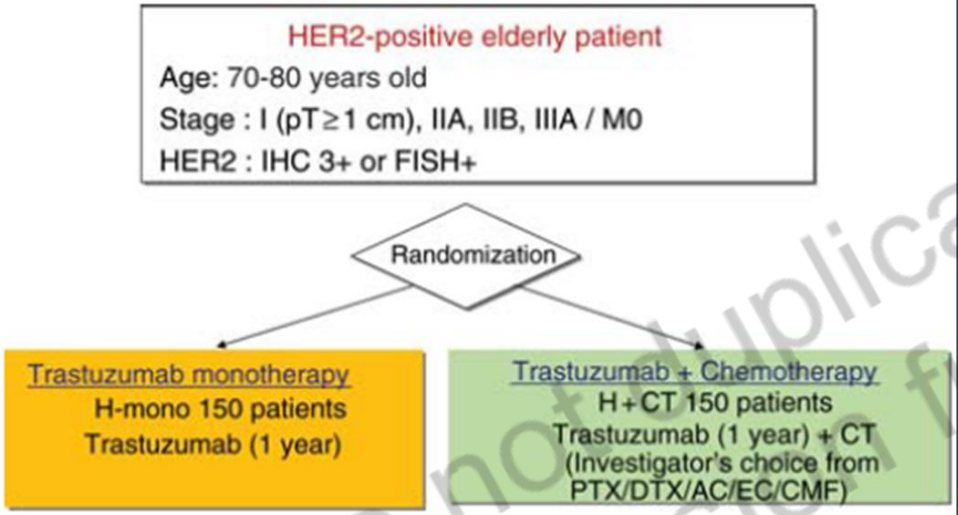
Clinical challenges in older breast cancer patient management

Limited level I evidence

- Under-representation of older patients in clinical trials
- Evidence derives mainly from:
  - ✓ Retrospective subgroup analyses
  - ✓ Extrapolation of trial results from younger patients
- Very few UNFIT patients included in older breast cancer patients-focused clinical trials

Randomized Controlled Trial of Trastuzumab Wi[illegible] or Without Chemotherapy for HER2-Positive Early Breast Cancer in Older Patients

Sawaki et al for the RESPECT study group. J Clin Oncol 2020



T vs T+CT

Three-year DFS: 89.5% vs 93.8% (HR, 1.36; 95% CI, 0.72 to 2.58; P = .51)

Three-year RFS: 92.4% vs 95.3% (HR, 1.33; 95% CI, 0.63 to 2.79; P=.53)

At 3 years, RMST differed by -0.39 months between arms (95% CI, 21.71 to 0.93; P = .56)

Common AEs were anorexia (7.4% v 44.3%; P , .0001) and alopecia (2.2% v 71.7%; P > .0001), and grade 3/4 nonhematologic AEs occurred in 11.9% versus 29.8% (P=.0003)

Clinically meaningful HRQoL deterioration rate at 2 months (31% v 48%; P= .016) and at 1 year (19% v 38%; P=.009).

CONCLUSION The primary objective of noninferiority for trastuzumab monotherapy was not met. However, the observed loss of survival without chemotherapy was < 1 month at 3 years. Therefore, and in light of the lower toxicity and more favorable HRQoL profile, trastuzumab monotherapy can be considered an adjuvant therapy option for selected older patients.

Older Patients with Advanced Breast Cancer

Medical Oncology

Etienne Brain, MD PhD
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INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY
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Conflicts of interest

- **Receipt of grants/research supports**
  - None
- **Receipt of travel supports**
  - AstraZeneca, Novartis, Pfizer, Pierre Fabre, Roche, Sandoz
- **Receipt of honoraria or consultation fees**
  - BMS, Eli Lilly, G1 Therapeutics, Pfizer, Sandoz, Seagen

Older ones: metastatic versus early-stage

1. **Past medical history**

   Survivors! With long-term toxicity of previous cancer treatments

   - *Cognitive impairment, cardiotoxicity, depression and anxiety, neurotoxicity, ototoxicity, imbalance & lack of coordination, osteoporosis, metabolic syndrome, second malignancy, sexual and vaginal dysfunction*

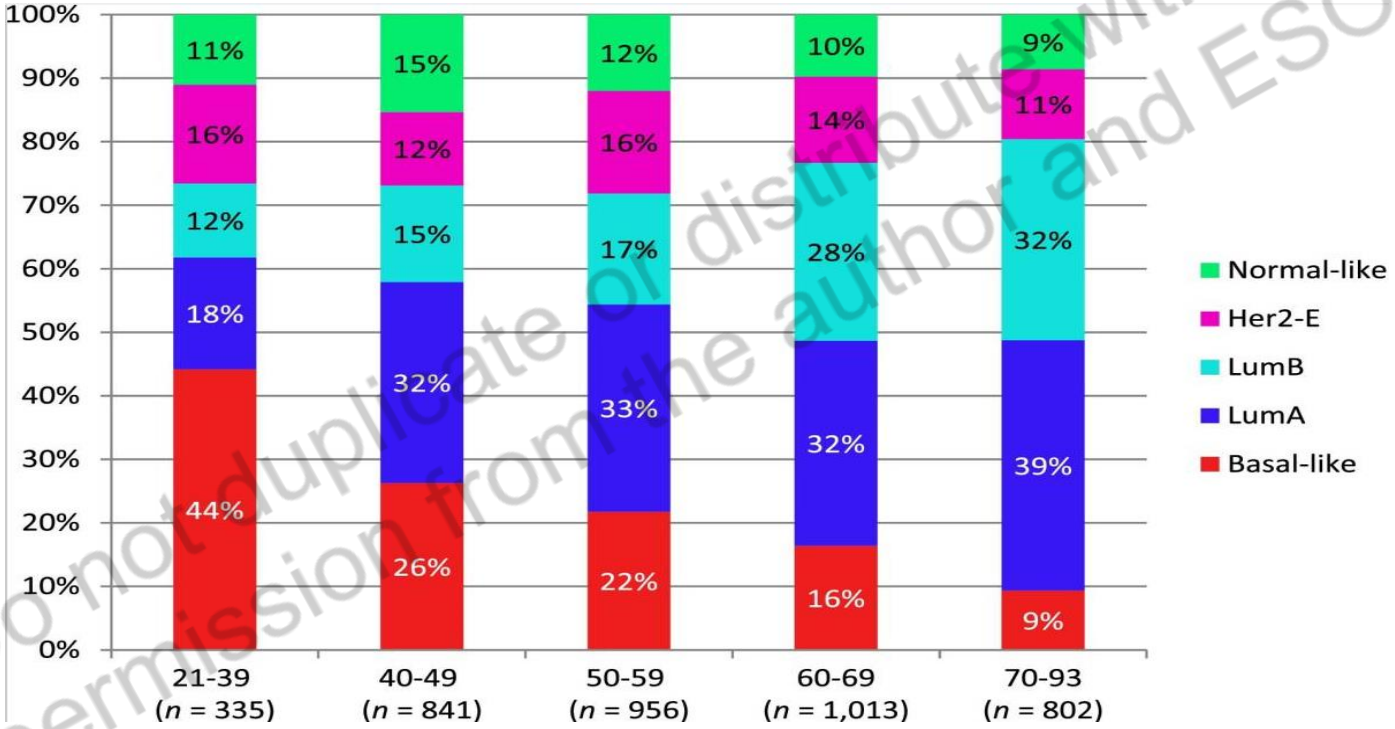
2. **Problems and complications due to comedication/polypharmacy**

   29% take > 7 drugs, NSAID/MTX, pain medications & cachexia (falls, fractures)

3. **Social and psychological aspects**

   Fear for pain and dependance, frailty and end of life aspects

BC biology according to age



de Kruijf Mol Oncol 2014, Jenskins Oncologist 2014

2 situations

- In favour of chemotherapy
  - TNBC
  - HER2+ ER-
- In favour of endocrine therapy
  - Monotherapy
  - Combinations

ABC5 | Bridging the Gap

Do we have high-quality data????

Chemotherapy

Endocrine therapy

Targeted therapy

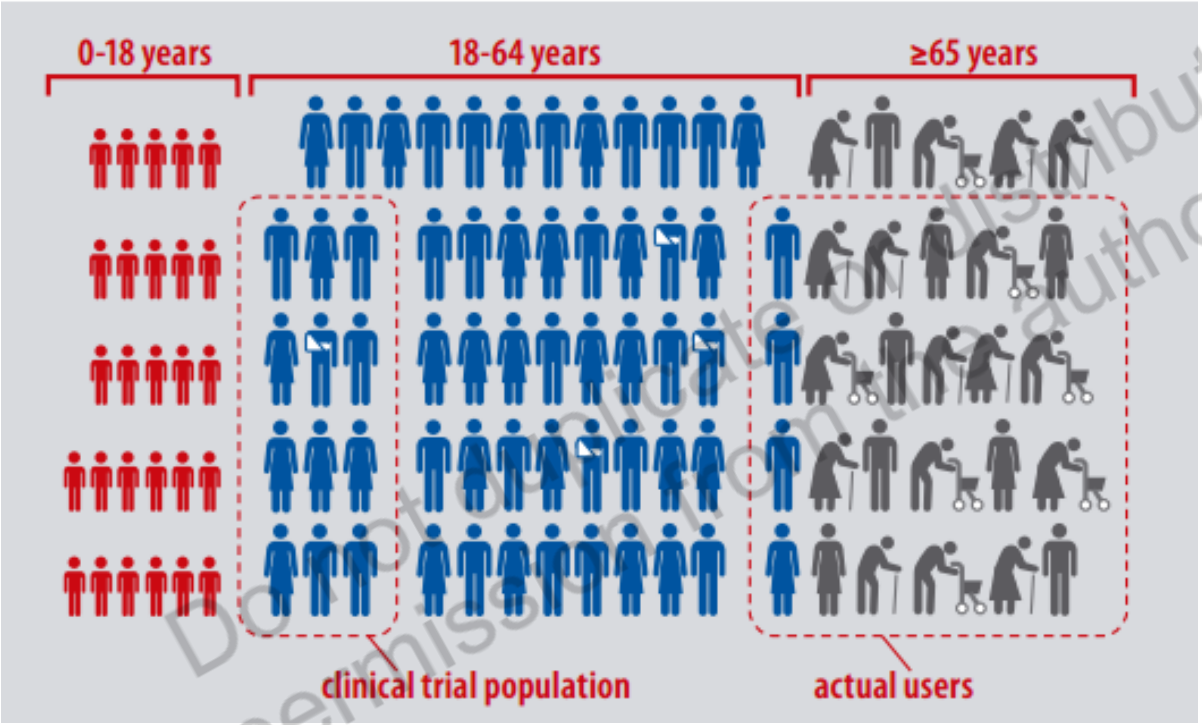
Few older adults included in registration studies! Breast cancer as an example

Agent Name	Approval	N	Age ≥ 65	N	Age ≥ 75
Palbociclib	2/2015	37	44%	8	10%
		86	25%		--
Everolimus	7/2012	290	40%	109	15%
Pertuzumab	6/2012	60	15%	5	1%
Eribulin mesylate	11/2010	121	15%	17	2%
Lapatinib	1/2010	34	17%	2	1%
		282	44%	77	12%
Ixabepilone	10/2007	45	10%	3	<1%
		32	13%	6	2.5%

Package Insert, "Geriatric Usage" section

Courtesy to Arti Hurria (adapted)

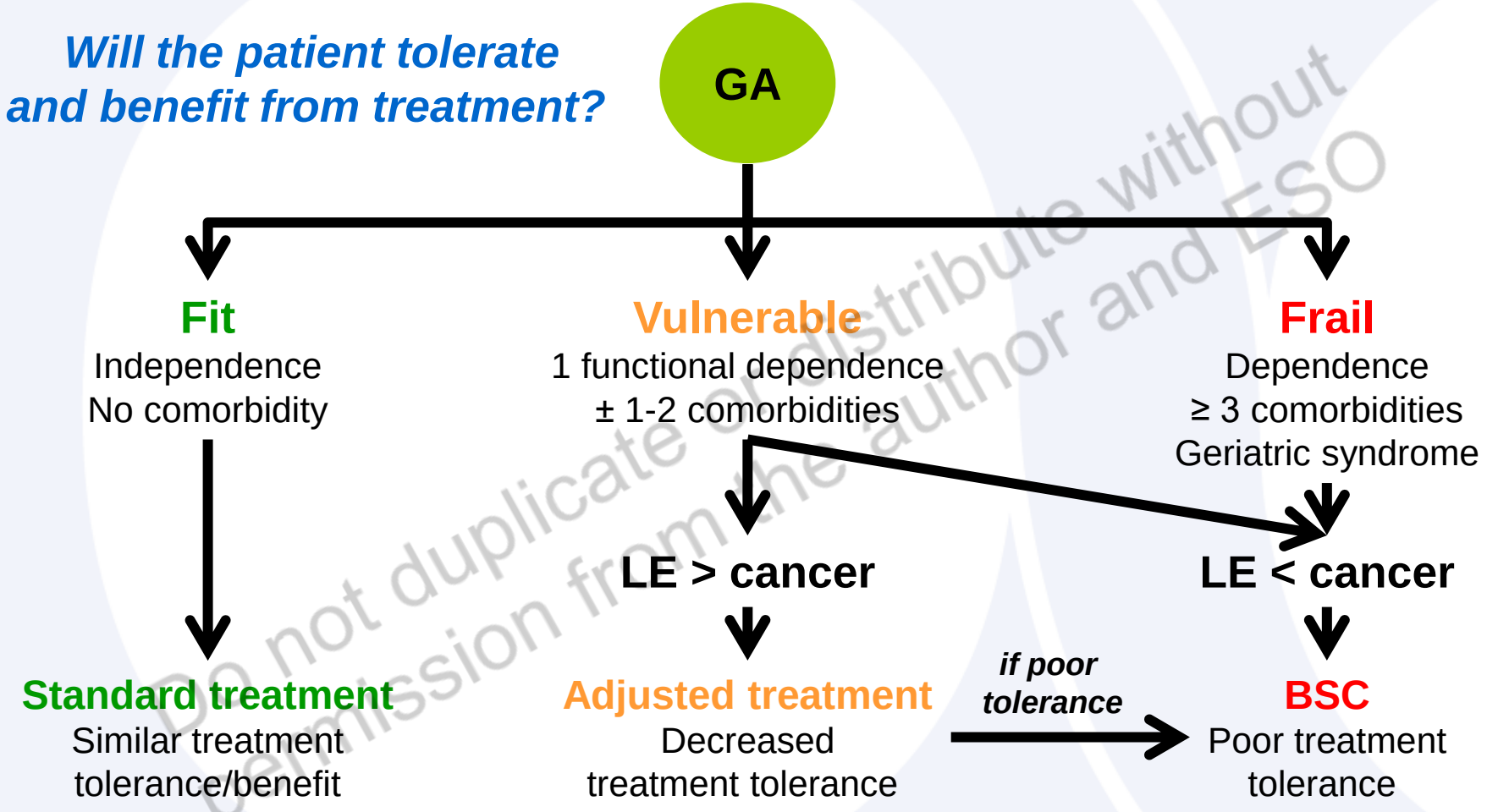
Trial population versus real-life data



In standard trials

- **Younger**
- **Less comorbidities**
- **Less organ dysfunctions**
- **Fitter**

Will the patient tolerate and benefit from treatment?



Balducci Oncologist 2000

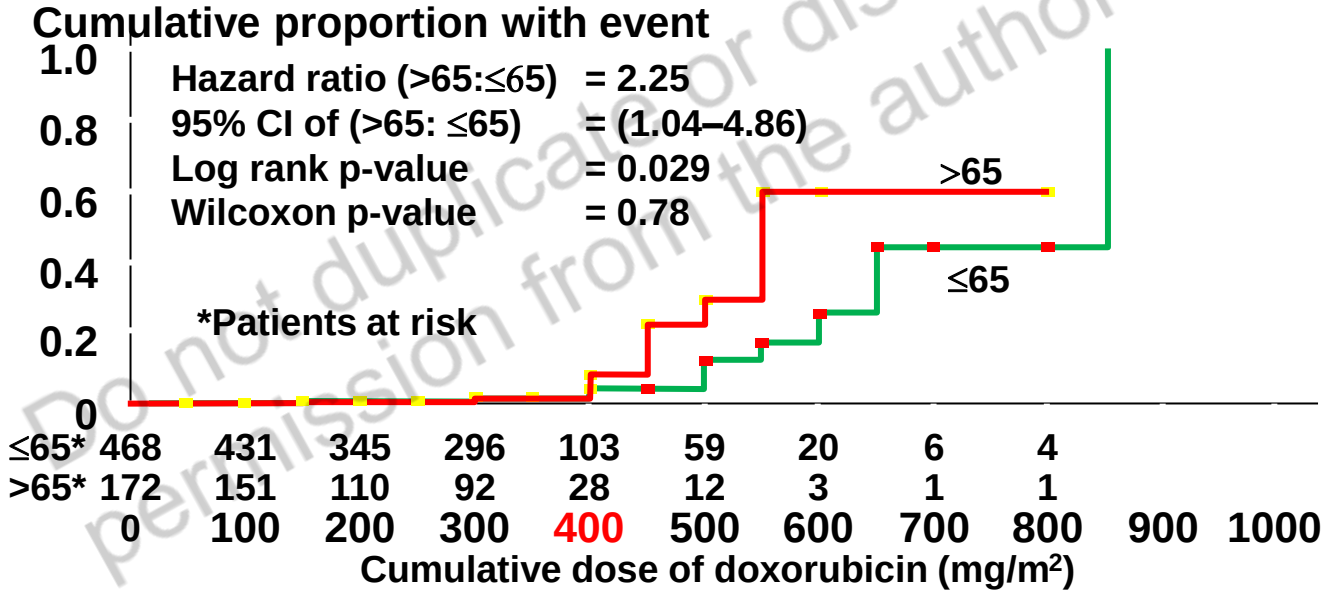
How many 70+ patients are fit?

- "Potentially" i.e. good results w/ screening tool (G8 > 14)
- MBC
  - 70% in large cohorts (Palomage EBCC 12, ASCO 2021)?
- EBC
  - 60% in large trials (ASTER 70s)?

Soubeyran PLOS 2014, Coussy SIOG 2015, Brain EBCC12 2020, Caillet ASCO 2021,

Doxorubicine, CHF and Age

- 630 patients (3 phase III) with 32 CHF
  - 26% >550 mg/m²
  - >50%: reduction of LVEF <30% w/ chemo
- HR_{age}
  - 2.25 (1.04–4.86) vs 3.28 (1.4–7.65) if >400 mg/m²



Swain Cancer 2003

Taxanes

Contents lists available at ScienceDirect

Cancer Treatment Reviews

journal homepage: www.elsevierhealth.com/journals/ctrv

Anti-Tumour Treatment

Taxanes in the treatment of breast cancer: Have we better defined their role in older patients? A position paper from a SIOG Task Force

L. Biganzoli[a,*], M. Aapro[b], Sibylle Loibl[c], Hans Wildiers[d], Etienne Brain[e]

- 2 cornerstones
  - Paclitaxel <80 mg/m²qw
  - Docetaxel q3w **but not standard @ 100 mg/m²!**
    - **Same pharmacokinetics**, but increased risk of neutropenia ± febrile if 65+
      - q3w 75 mg/m² grade 3-4 ANC/FN: 63%/16% vs 30%/0%
      - qw 35 mg/m² > 50% grade ≥ 3 → RD: 26 mg/m²
      - q2w 50 mg/m² GERICO-04
  - Grade 3-4 neurosensory/motor toxicity 28%/14% (vs <18%/<8% if <65)
- Nab-paclitaxel
  - Efficacy comparable with solvent-based taxanes
  - No need for steroid premedication

Del Mastro Ann Oncol 2005; ten Tije J Clin Oncol 2005; Girre Ann Oncol 2008; Biganzoli Cancer Treat Rev 2016

VOLUME 34 · NUMBER 20 · JULY 10, 2016
JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

A true predictive model for chemo-related grade 3-5 toxicity

Validation of a Prediction Tool for Chemotherapy Toxicity in Older Adults With Cancer

Arti Hurria, Supriya Mohile, Ajeet Gajra, Heidi Klepin, Hyman Muss, Andrew Chapman, Tao Feng, David Smith, Can-Lan Sun, Nienke De Glas, Harvey Jay Cohen, Vani Katheria, Caroline Doan, Laura Zavala, Abrahm Levi, Chie Akiba, and William P. Tew

CARG
CANCER & AGING RESEARCH GROUP

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PREDICTION TOOL

Gender: Select
Patient's Age:
Patient's Height: Select Select
Patient's Weight: Select Select
Cancer Type: Choose
Dosage: Choose *
Number of chemotherapy agents: Choose
Hemoglobin: Select a value
How is your hearing (with a hearing aid, if needed)?: Choose
Number of falls in the past 6 months: Choose
Can you take your own medicines?: Choose
Does your health limit you in walking one block?: Choose
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?: Choose
Select Serum Creatinine: Choose
Creatinine Clearance: **
Submit
Toxicity Score:
Risk of Chemotherapy Toxicity:
What does this mean?
* Dose delivered with first dose for chemotherapy
** Jelliffe formula

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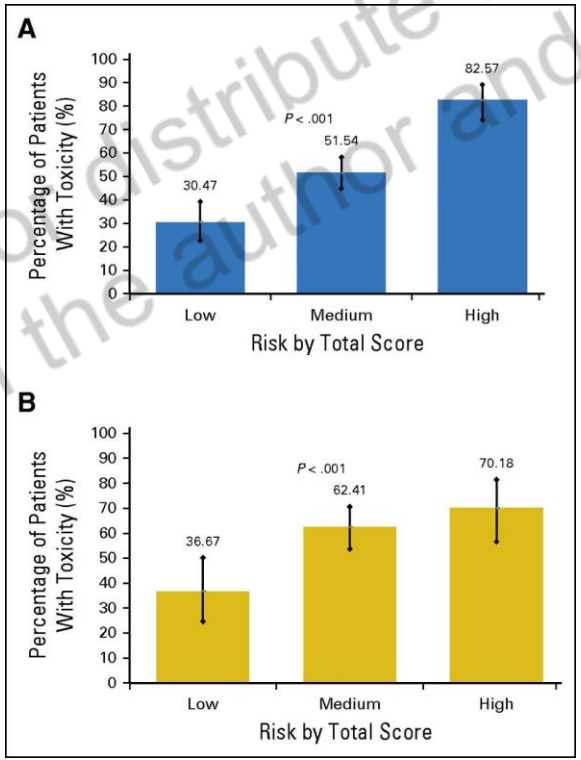
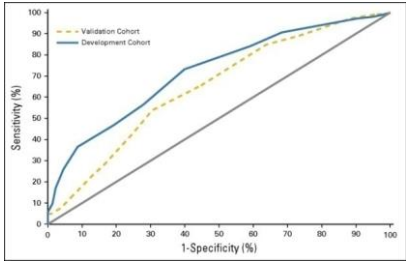


1. 58% grade ≥ 3 toxicity
2. Risk increased w/ increasing risk score
3. AUC/ROC 0.65 (95%CI 0.58-0.71) ~ development cohort 0.72 (95%CI 0.68-0.77) (P = .09)
4. No association between PS and chemo toxicity (P = .25)

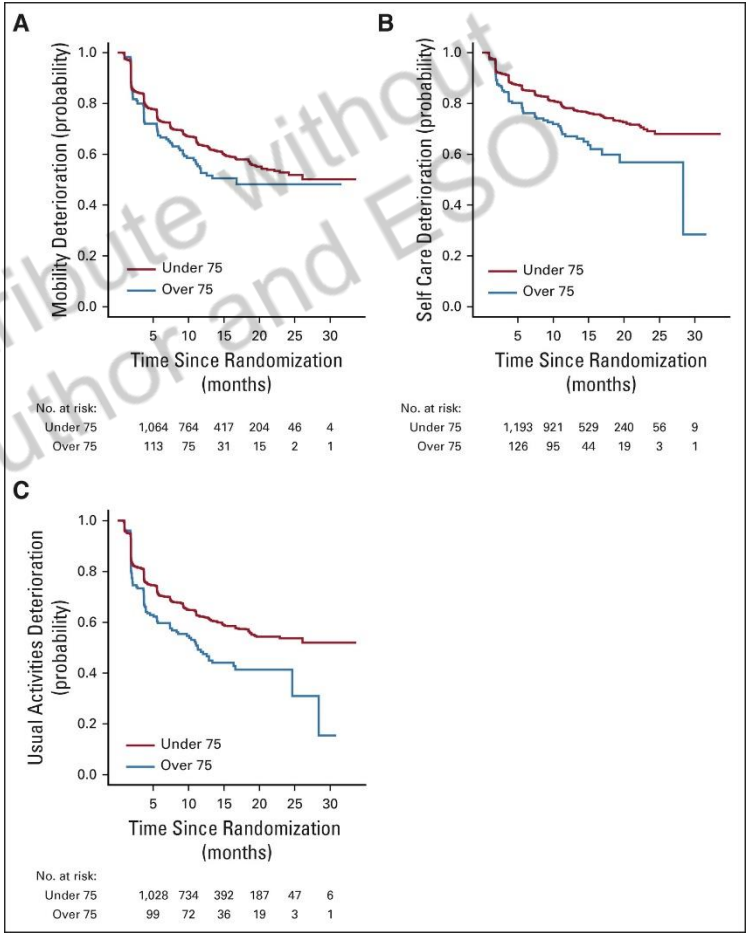


Hurria J Clin Oncol 2016

original reports

Outcomes of Older Women With Hormone Receptor–Positive, Human Epidermal Growth Factor Receptor–Negative Metastatic Breast Cancer Treated With a CDK4/6 Inhibitor and an Aromatase Inhibitor: An FDA Pooled Analysis

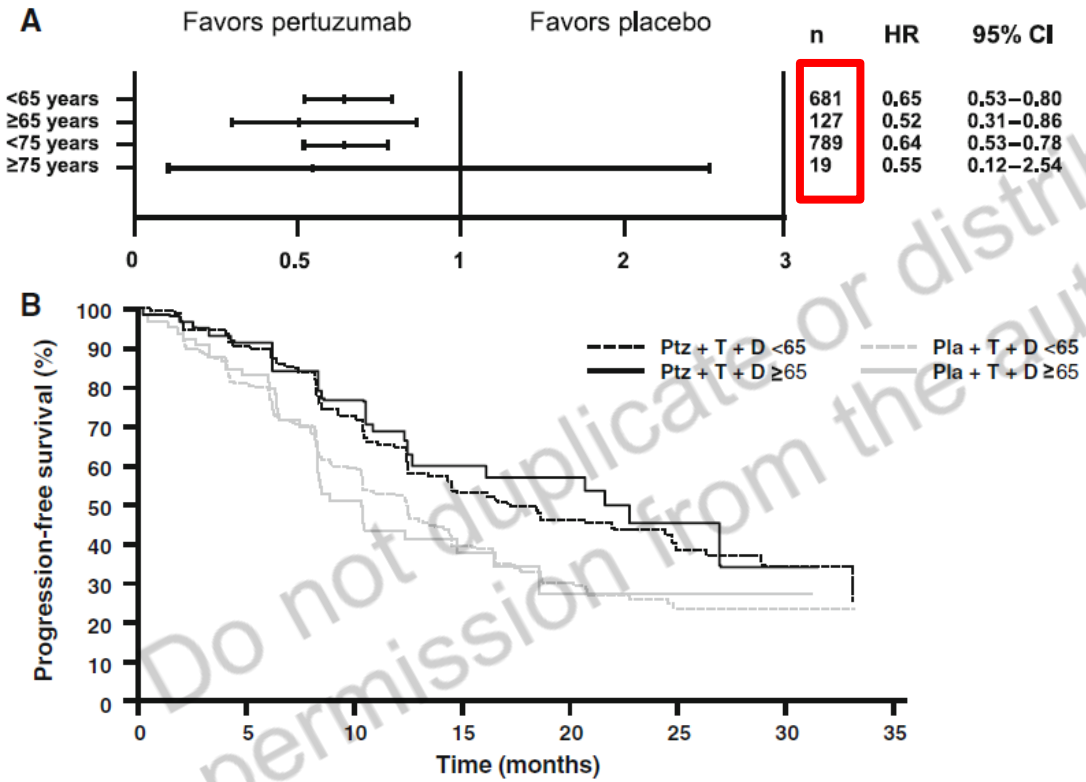
Lynn J. Howie, MD[1]; Harpreet Singh, MD[1]; Erik Bloomquist, PhD[1]; Suparna Wedam, MD[1]; Laleh Amiri-Kordestani, MD[1]; Shenghui Tang, PhD[1]; Rajeshwari Sridhara, PhD[1]; Jacqueline Sanchez, MA[1]; Tatiana M. Prowell, MD[1]; Paul G. Kluetz, MD[1]; Belinda L. King-Kallimanis, PhD[1]; Jennifer J. Gao, MD[1]; Amna Ibrahim, MD[1]; Kirsten B. Goldberg, MA[1]; Marc Theoret, MD[1]; Richard Pazdur, MD[1]; and Julia A. Beaver, MD[1]



1. CDK4/6 inhibitor + AI as 1st line treatment of HR+ MBC in older women → **similar efficacy** benefit as seen in younger women
2. Incidence and severity of Grade 1-4 AEs similar between age groups, **but** **greater SAEs and discontinuations occurred in patients ≥75 (89% vs 73%)**
3. EQ-D5 → **decline in HRQoL** regardless of treatment
4. Need for inclusion of greater numbers of patients ≥70 in **clinical trials**

Howie JCO 2019

Pertuzumab



CLEOPATRA

808 patients

→ 127 (16%) 65+

→ 19 (2%) 75+

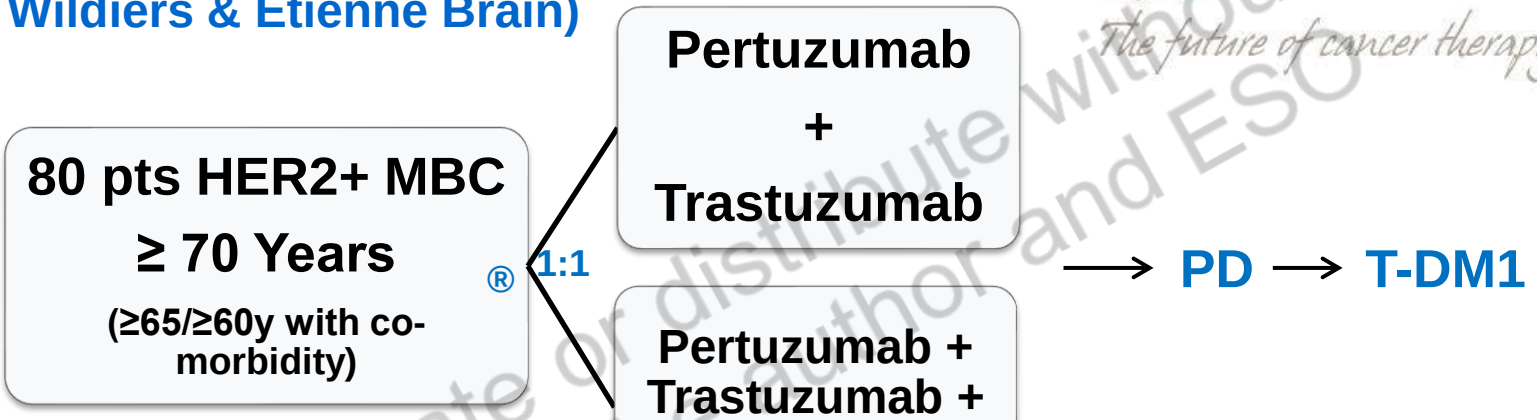
More frequent in elderly patients

- **Any grade**: diarrhea, asthenia, fatigue, anorexia, vomiting and dysgueusia
- **Grade 3**: diarrhea, peripheral neuropathy
- **Dose intensity**: 12% dose escalation , 31% dose reduction, 20-30% G-CSF

Miles Breast Cancer Res Treat 2013

EORTC 75111-10114

(Co-PI Hans Wildiers & Etienne Brain)



Primary endpoint
PFS at 6 months of PH or PHM

Secondary endpoints
OS, BCSS, toxicity, RR (RECIST v1.1), HRQoL, evolution of GA during treatment

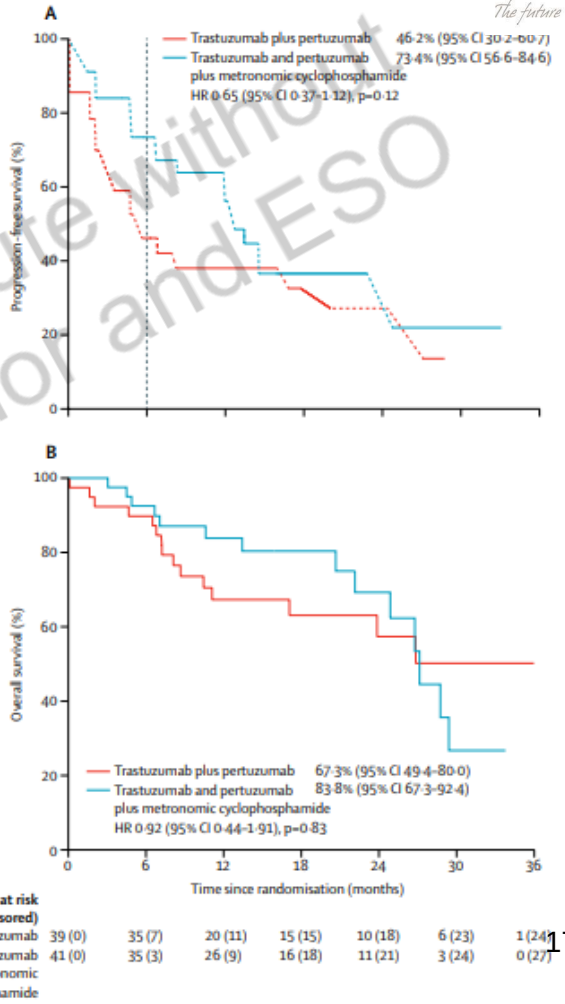
Stratification: ER/PgR, previous HER2 treatment, G8

Pertuzumab	**840 mg loading dose, further 420 mg q3w iv**
Trastuzumab	**8 mg/kg loading dose, further 6 mg/kg q3w iv**
Chemotherapy	**Metronomic chemotherapy: cyclophosphamide 50 mg/d po continuously**
On progression	**Option to have T-DM1** *(3.6 mg/kg iv q3w)* **till progression**

Wildiers Lancet Oncol 2018

Pertuzumab and trastuzumab with or without metronomic chemotherapy for older patients with HER2-positive metastatic breast cancer (EORTC 75111-10114): an open-label, randomised, phase 2 trial from the Elderly Task Force/Breast Cancer Group

Hans Wildiers, Konstantinos Tryfonidis, Lissandra Dal Lago, Peter Vuylsteke, Giuseppe Curigliano, Simon Waters, Barbara Brouwers, Sevilay Altintas, Nathan Touati, Fatima Cardoso, Etienne Brain



Elderly/frail HER2+ MBC population

TP + metronomic CT > TP
(7-month longer median PFS: 12.7 vs 5.6)

Acceptable safety profile

T-DM1 at progression active

Wildiers Lancet Oncol 2018

EUSOMA
European Society of Breast Cancer Specialists

Improving Breast Cancer Care in Europe

EJC The official journal of EUSOMA

Management of elderly patients with breast cancer: updated recommendations of the International Society of Geriatric Oncology (SIOG) and European Society of Breast Cancer Specialists (EUSOMA

Laura Biganzoli, Hans Wildiers, Catherine Oakman, Etienne Brain, Bruno Cutuli, Catherine Terret, Mar

As the mean age of the global population in clinical practice. Management decisi management of older individuals with heterogeneous population. In 2007, the provide evidence-based recommendatio multidisciplinary SIOG and European S and update the 2007 recommendation competing causes of mortality, ductal ca treatment, and male breast cancer. Re surgery, radiotherapy, neoadjuvant and

Cancer Treatment Reviews 43 (2016) 19–26

Contents lists available at ScienceDirect

Cancer Treatment Reviews

ELSEVIER

Anti-Tumour Treatment

Taxanes in the treatm role in older patients'

L. Biganzoli [a,*], M. Aapro [b], S

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[c] German Breast Group, Sana-Klinikum Offenb
[d] University Hospitals Leuven, Leuven, Belgium
[e] Institut Curie – Hôpital René Huguenin, Saint

Contents lists available at ScienceDirect

Journal of Geriatric Oncology

ELSEVIER

HER2-targeted treatment for older patients with breast cancer: An expert position paper from the International Society of Geriatric Oncology

Etienne Brain [a,*], Philippe C
Lissandra Dal Lago [f], Hans W

Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG)

Laura Biganzoli, Nicolò Matteo Luca Battisti, Hans Wildiers, Amelia McCartney, Giuseppe Colloca, Ian H Kunkler, Maria-João Cardoso, Kwok-Leung Cheung, Nienke Aafke de Glas, Rubina M Trimboli, Beatriz Korc-Grodzicki, Enrique Soto-Perez-de-Celis, Antonio Ponti, Janice Tsang, Lorenza Marotti, Karen Benn, Matti S Aapro, Etienne G C Brain

SIOG
INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY

Biganzoli Lancet Oncol 2012 & 2021; Cancer Treat rev 2016; Brain J Ger Oncol 2019

SIOG
INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY

Tumour extent
TNM

General health status
Geriatric assessment
Life expectancy
Treatment toxicity

Tumour biology
Pathology
Gene expression profile

Patient preference & acceptability

Acceptability & willingness

West Haven Veterans Affairs

226 patients 60+: attitudes toward burden of treatment, possible outcomes, and likelihood
- Limited life expectancy (cancer, congestive heart failure, or chronic obstructive pulmonary disease)
- Burden of treatment (length of the hospital stay, extent of testing, and invasiveness of interventions)

1. Low-burden treatment (restoring participant's current state of health) vs no treatment resulting in **death**

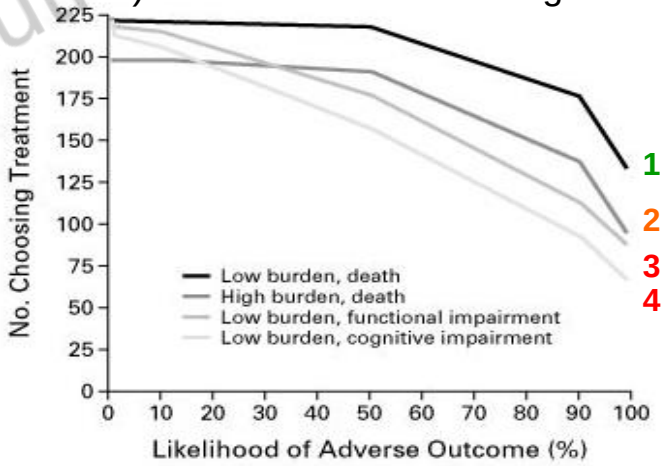
98.7% accept treatment

2. High-burden treatment vs no treatment resulting in **death**

11% decline

3 & 4. Low-burden treatment vs survival with **severe functional or cognitive impairment**

74-89% decline



The likelihood of adverse functional and cognitive outcomes of treatment requires explicit consideration in older ones

Fried NEJM 2002


Reuters

Impact of GA on treatment decision & interventions

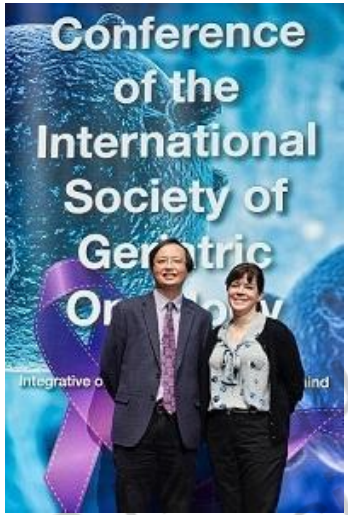
- Oncological decision before or after "some kind of" geriatric assessment
  - **40% modification** of initial treatment plan
  - **66% w/ less intensive treatment**
  - Functional & nutritional status +++
  - Potential interventions in **> 70%** patients

Hamaker Acta Oncol 2014

SIOG 2021
INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY

ANNUAL CONFERENCE
VIRTUAL
4-5 NOV





Optimising treatment in older cancer patients is precision medicine too!

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