Aspetti organizzativo-gestionali Breast Unit

Rete Oncologica piemontese

Torino, 9 Luglio 2109

IEO
European Institute of Oncology

Organizzazione

8 Programmi, “verticali”

(Mammella, Torace, Digestivo, Urologia, Gynecologia, Testa&Collo, Ematologia, Melanoma&Sarcoma&Tumori Rari)

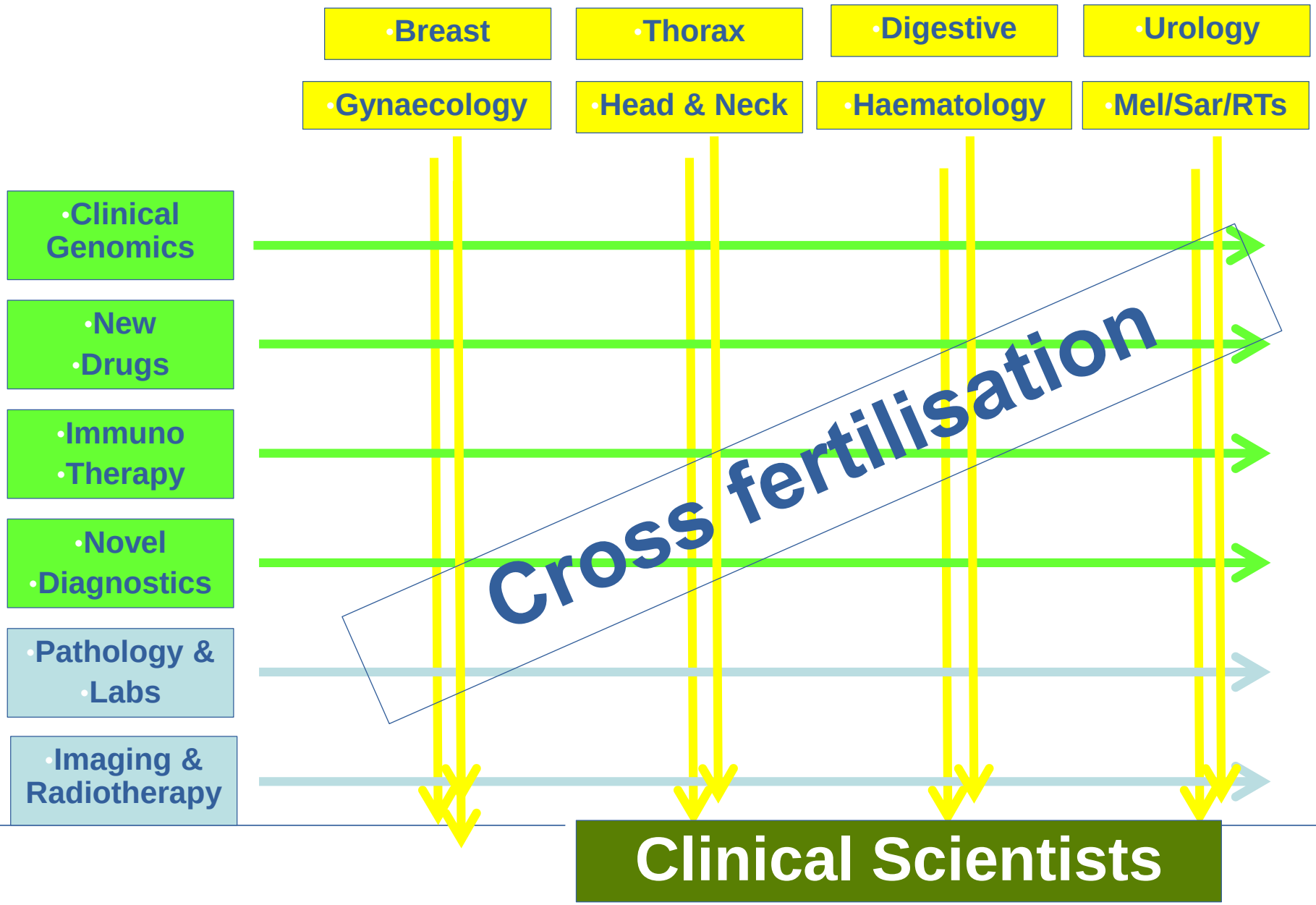
4 Programmi di Ricerca, “orizzontali”

(Genomica Clinica, Nuovi Farmaci, Immunoterapia, Diagnostica Molecolare)

2 Departmenti Clinici

(Imaging&Radioterapia, Anatomia Patologica&Lab)

IEO. La matrice



Attività

288 letti

- **> 17,800 ricoveri**
- **> 14,600 interventi chirurgici maggiori**
- **> 1,200 chirurgia robotica**
- **> 5,700 Day-Surgery (Pazienti)**
- **> 8,300 interventi chirurgici minori**

- **154,000 visite**

- **> 43,000 esami istopatologici**
- **> 105,000 procedure di imaging**
- **> 20,000 Day-Hospital (accessi)**
- **> 3,500 Radioterapia (Pazienti)**

Attività Chirurgica

	Procedures
Breast Surgery	3753
Plastic and Reconstructive Surgery	1922
Urology Surgery	1793
Thoracic Cancer Surgery	1634
Interventional Radiology	1233
Head&Neck Surgery	927
Gynecology Surgery	902
Preventive Gynecology	834
Sarcoma Surgery	749
Digestive/Hepato-biliary Surgery	715
.....	...
Total	**14679**

Programma Senologia

Senologia Chirurgica

Day-Surgery

Chirurgia Ricostruttiva

Senologia Medica

Day-Hospital

Prevenzione e Genetica Oncologica

Sviluppo di Nuovi Farmaci per Terapie Innovative

Imaging
APA
Radioterapia
Cardio-oncologia
Terapie palliative
Psico-oncologia

Obiettivi

Certificazione

Integrazione

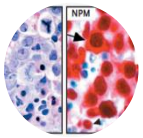
Budget unico

Tumor Board Clinico

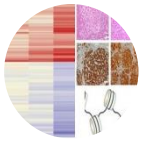
Molecular Tumor Board

Verifica da parte di Amministrazione, Direzione Scientifica, Direzione Sanitaria e Ufficio Qualità

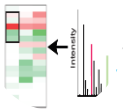
IEO Attività di Ricerca



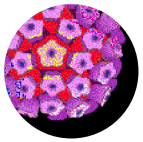
Experimental haematology



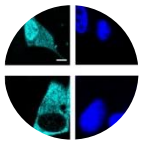
Oncogenes, chromatin and cell Cycle control



Analysis of gene expression regulation by quantitative functional protemics

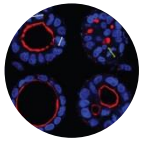


Virus controlled cell processes and biology of tumorigenesis

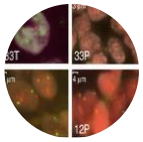


Molecular carcinogensis and stem cell biology

Target identification and validation

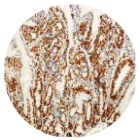


Molecular mechanisms of asymmetric cell division

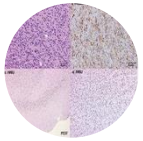


Chromatin alterations in tumorigenesis

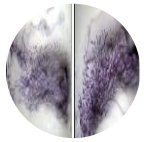
Transcriptional control of inflammation and cancer



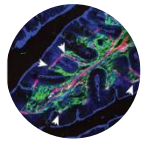
Epigenetic mechanisms in stem cell differentiation and oncogenesis



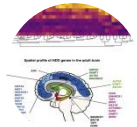
Glioblastoma biology and brain metastases



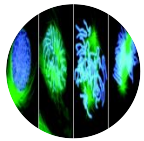
Molecular mechansisms of cancer and aging



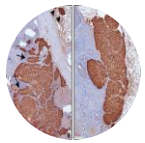
Immunobiology of dendritic cells and immunotherapy



Epigenetics of stem cells



Chromosome segregation



Biology of ovarian cancer

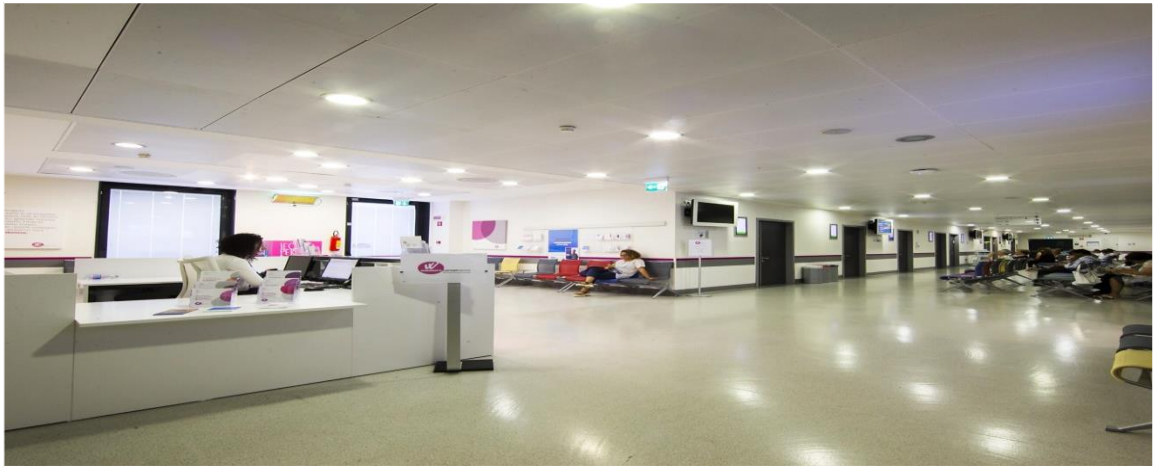
Principal Investigators	16
Staff Scientists	15
Postdoc Fellows	86
Ph.D Students	58
Technicians	31
Undergraduate students	12
Visitors	11

TOTAL STAFF229

Women's Cancer Center

The Women's Cancer Center gathers in one functional and welcoming space all the IEO oncological and medical competences linked to the gynecological and breast cancers; this highly specialized service provide our female patients with the best treatment possible from the prevention, to the diagnosis, treatment and follow up

The IEO Gynecology and Breast Multidisciplinary Programs (surgeons, oncologists, pathologists, imaging specialists, radiotherapists, geneticists, nutritionists, psychologists, sexologists and fertility specialists) will work together to try to answer all the problems that a woman facing an oncological disease has to deal with and to support her all the way through her clinical path here at IEO



women's cancercenter
IEO Istituto Europeo di Oncologia

- Counseling oncogenetico
- Benessere
- Nutrizione
- Oncofertilità
- Psiconcologia
- Sessuologia integrata
- Agopuntura

Clinical Trial Office

Coordinamento con i ruoli Amministrativi

Scientific Review Board

Comitato Etico/

Ufficio Regolamentazione StudiClinici

Clinical Research Platform

Reporting

Scientific Review Board

- Valutazione di tutti i progetti di ricerca:
  - Priorità
  - Rilevanza clinica
  - Fattibilità & Logistica

- Selezione per attivazione e conduzione di studi che siano rilevanti per:
  - Pazienti
  - Conoscenza Scientifica
  - Reputazione

- *Record compliance of the conduct of specific trials (patient accrual)*
- *Check (for some trials of strategic importance for each of the Programs) the reasons for NOT INCLUSION OF potentially eligible patients*
- *Draw attention to areas of strategic relevance for which trials ARE MISSING*

Clinical Reseach Platform

- Coordination
- Data Management
- Biostatistics (and Computational Science)
- Research Nursing
- Regulatory Affairs
- Research Pharmacy
- Medical Writing
- Dedicated Administration
- Tumor Registry

Assistance and Support to PI and to All Investigators

Radioterapia personalizzata nel carcinoma della mammella

Rete Oncologica piemontese

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NEED FOR RT IN EUROPE. ESTRO-HERO ESTIMATION

Tumor site	RT courses (2012)	Increase in number (2025)	Increase in rate (%)
Breast	**396,891**	**40,524**	**10.2**
Lung	315,197	56,558	17.9
Prostate	243,669	59,493	24.4
Head&Neck	108,194	13,337	12.3
Rectum	99,493	18,314	18.4
Lymphoma	74,852	9871	13.3
Others	.....	.....	.....

About 60% of the patients with BC receives adjuvant RT

After BCS this rate increases up to 90-95%

Breast cancer is the first or second cancer treated by RT in all the European Countries

Borras JM et Al. Radiother Oncol 2016

Current challenges

- **Evolution of radiation techniques**

More personalized and precise delivery which incorporate 3D (4D) individual patient characteristics (tumour location and patient anatomy) in the breast conservation or post-mastectomy setting

This results in a more uniform distribution of the dose across the targeted volume, with decreasing both acute and long-term toxicities by less exposure to surrounding critical normal tissue such as heart, lung, and contralateral breast

Lymphedema

Chronic pain, functional impairment, psychological distress, poor QoL

Overall incidence: 21.4%

Four times risk after ALND (20%) than SNb (5.6%)

Higher risk in ALND + AxRT (41%)

Reported incidence varied in literature due to the lack of common diagnostic criteria :

< 5% to > 50%

Body Mass Index (BMI)

Lack of breast reconstruction

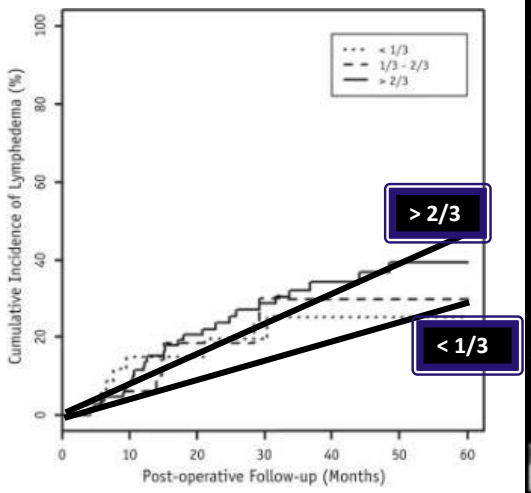
Adjuvant and neoadjuvant CT

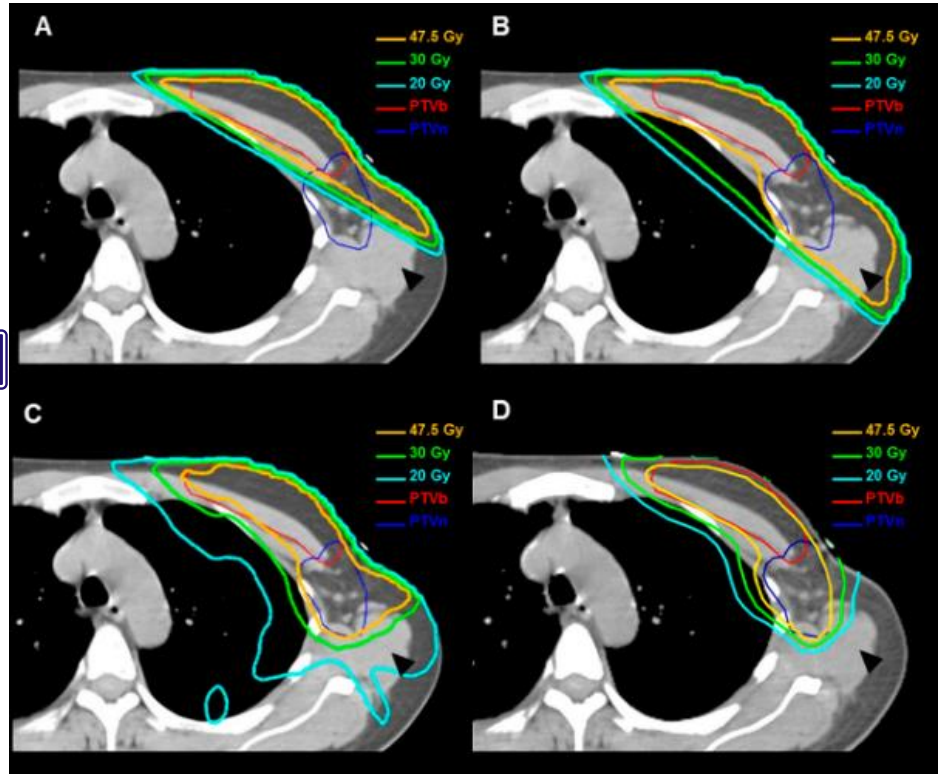
Subclinical edema

Cellulitis

DiSipio T et al, Lancet Oncol 2013

Lateral border of the SC field

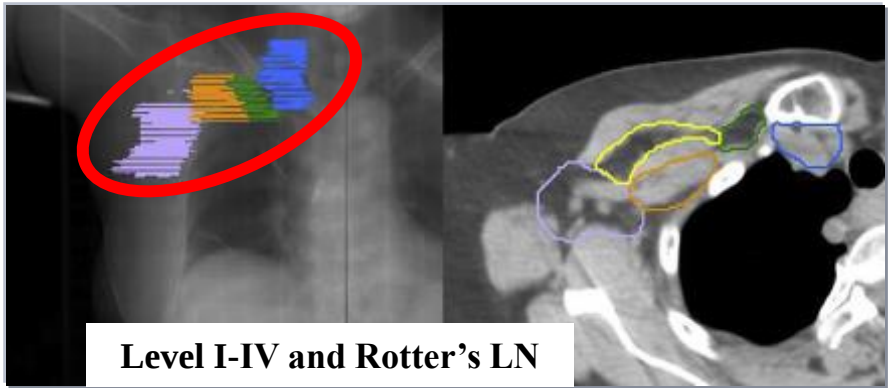


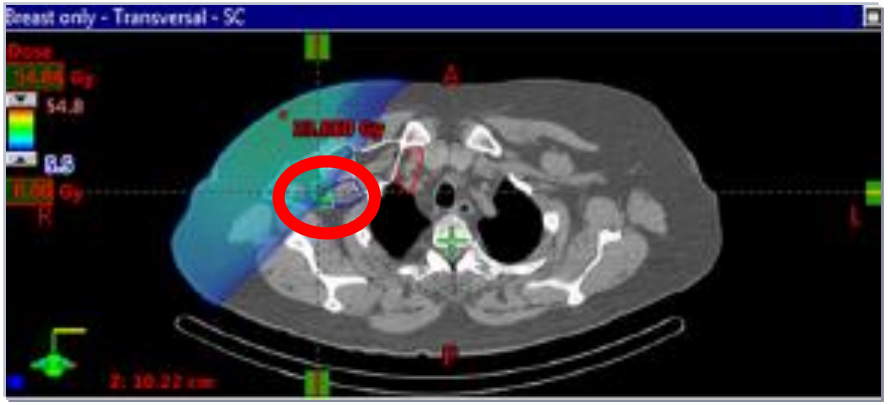


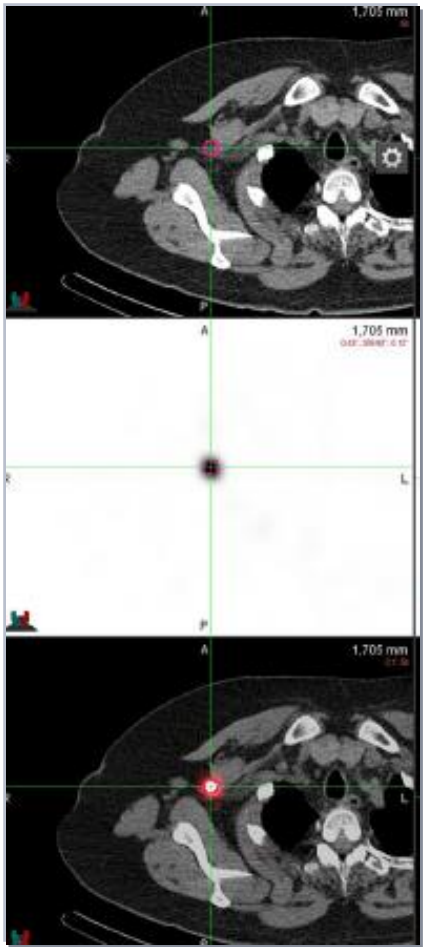
A. Conventional
B. Modified
C. IMRT
D. Protontherapy

Chandra RA et al, Int J Radiat Oncol Biol Phys 2015

Lymph Node draining the arm (ARM node)







Wang W et al, Radiother Oncol 2018

AMAROS (EORTC) trial

1425 patients with N+, 744 ALND and 681 ART

Intention to treatment study (85% received treatment)

Median follow-up 6.1 years

Axillary relapse:

Significantly less rate of lymphedema

at 5-ys 13.6% versus 28.0%

At 10ys

ALND	**0.93%**	**(7 patients)**
ART	**1.82%**	**(11 patients)**

Donker M et al, Lancet Oncol 2014; Rutgers EJT et al, SABCS 2018

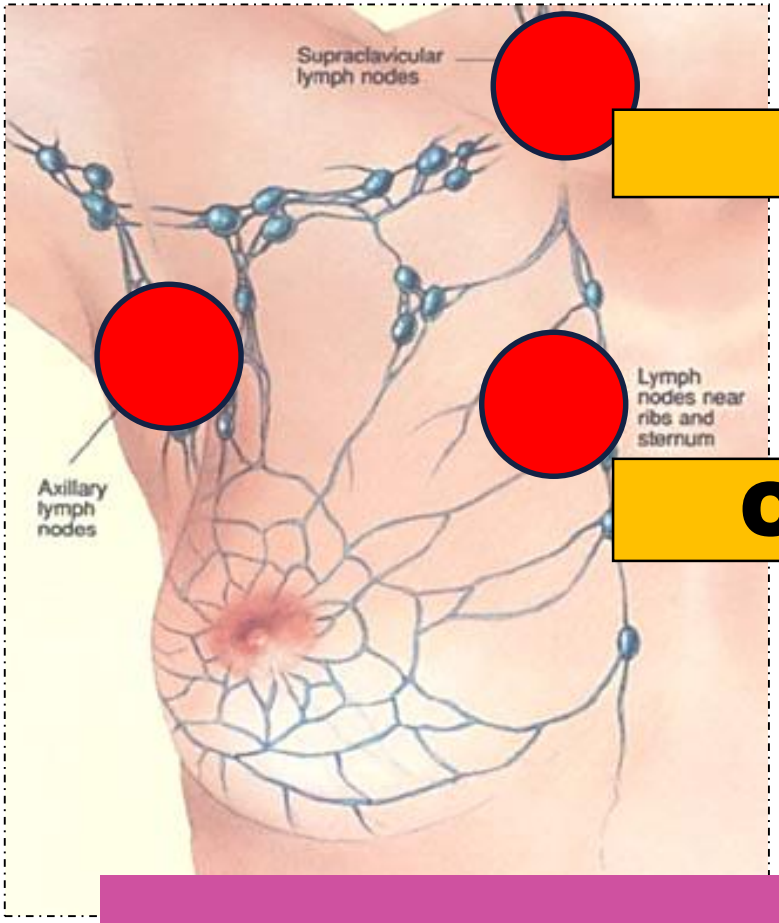
Current challenges

- **Personalization of volume, dose and fractionaction**

The role of RNI will further evolve by more mature data available

APBI is a heterogeneous approach with diverse delivery techniques, each with its own complex sets of clinical, technical, and dosimetric considerations

Moderate WBI hypo-fractionaction (with or w/out concomitant boost) is now considered efficacious and safe for almost all the patients. Further data may allow for even shorter radiation schedules



- More than 4 +ve nodes

At any case

- From 1 to 3 +ve nodes
- Internal Mammary Chain

Only if poor features

-
-
-

???

When RNI ?

Trials RNI in N+ patients (in progress)

Study	Design
POSNOC 2014-….	To investigate whether omitting adjuvant axillary treatment is non-inferior to ALND or RNI in ≤T2, N+ (1 to 2 macromets) 1900 patients, BCS or mastectomy
BOOG 2013-07 2014-….	To investigate whether completion axillary treatment is non-inferior to axillary treatment (ALND or RNI) in ≤T2, up to 3 N+ (micro/macro) 878 patients, mastectomy

Trials RNI after NAC (in progress)

Study	Design	Primary End Point
NSABP B51 2013-….	RNI vs no treatment in pCR after NAC	IBC-RFI
ALLIANCE A011202 2015-….	RNI vs ALND in persistent N+ after NAC	IBC-RFI
MA-39 2015-….	RNI vs no RNI in low-risk disease (biomarkers)	ND in DFS

UK IMPORT LOW Trial

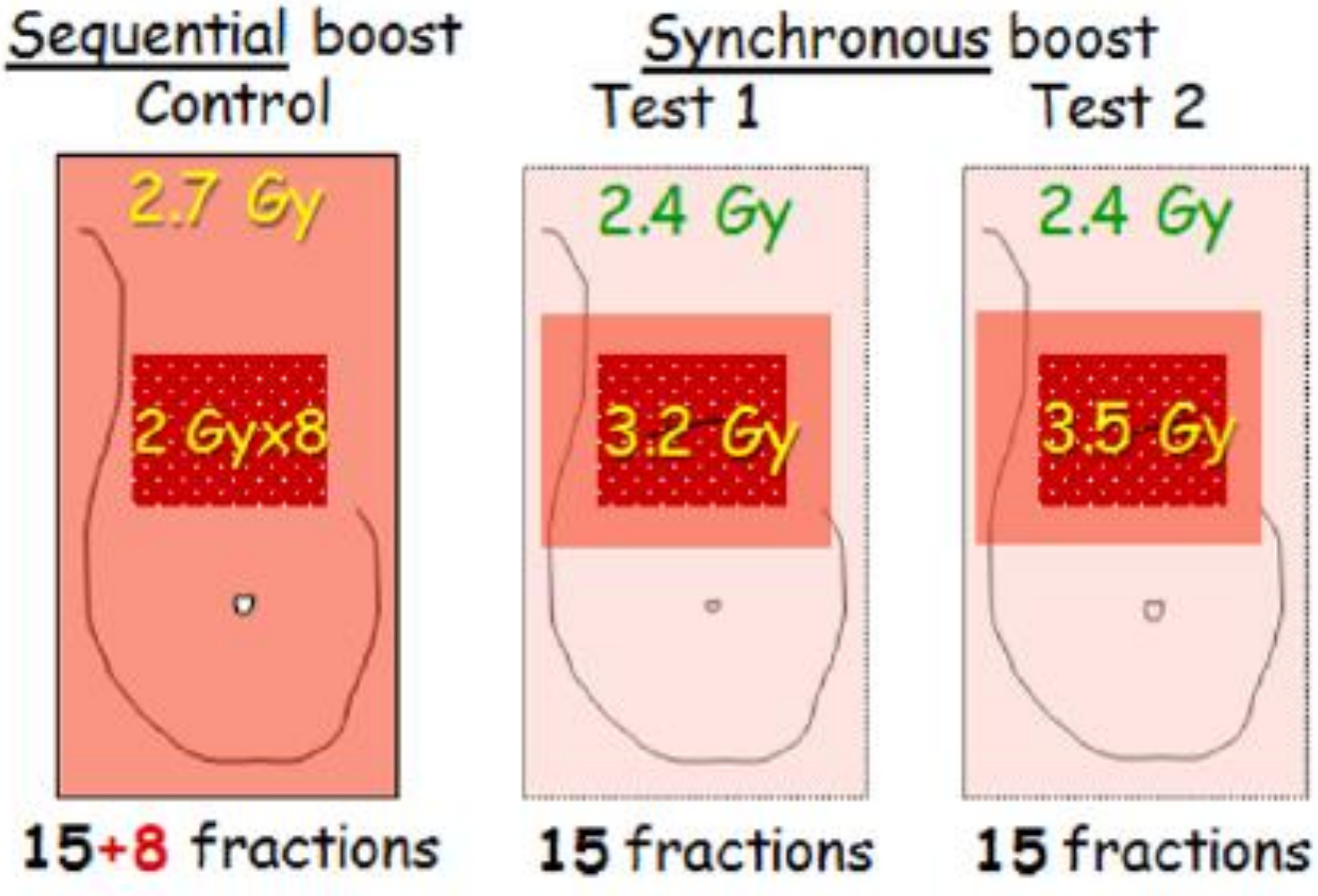
Control Group: Whole breast	Test Groups: Partial breast	
	Group 1	Group 2

- 1) IBTR Control (WBI) 1.1%
- 2) IBTR Reduced Dose (Group 1) 0.2%
- 3) IBTR PBI only (Group 2) 0.5%
- Equivalent or fewer adverse effects in 2)&3)

15 Fractions	15 Fractions	15 Fractions

Coles CE et al, Lancet 2017

UK IMPORT HIGH Trial



Can we push more in HFRT?

UK FAST Forward trial

28.5 Gy (5.7 x 5 fs, 1 week)
30.0 Gy (6.0 x 5 fs, 1 week)

TP optimised with 3D dose compensation to ensure
>95% PTV received 95%,
<5% PTV received 105%,
<2% PTV received 107%,
and global Dmax <110% of the prescribed dose

Stereotactic Body RT (SBRT)

Elderly patients

Once-weekly HFRT

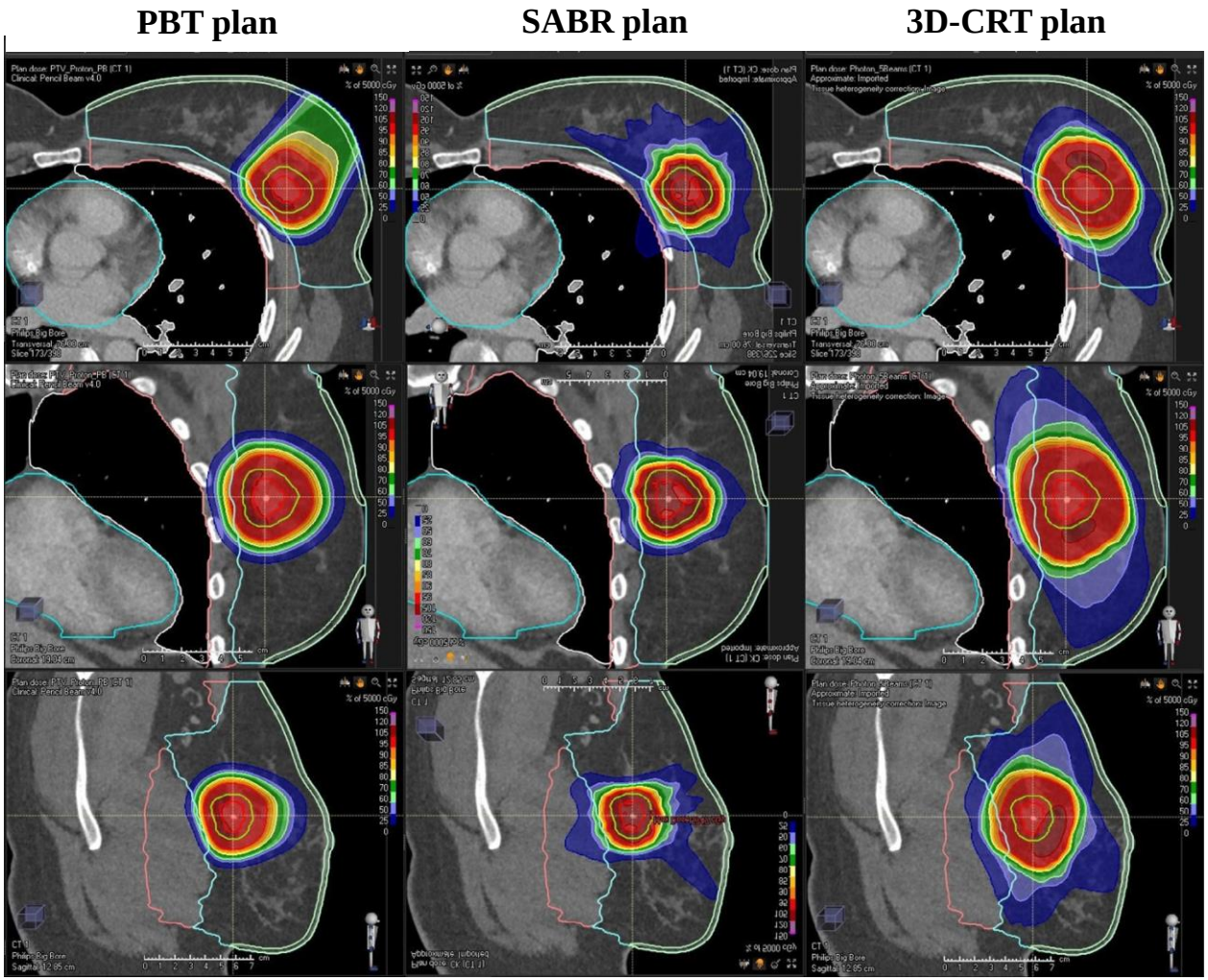
5.75 Gy x 4 fs (17 days)
6 Gy x 6 fs (18 days)

5.0 Gy x 5 fs (5 weeks)
6.0 Gy x 5 fs (5 weeks)
6.25 Gy x 5 fs (5 weeks)
6.5 Gy x 5 fs (5 weeks)
5.0 Gy x 6 fs (6 weeks)

SABR appealing

SABR in the setting of neoadjuvant and adjuvant RTy

Its use comes with a number of radiobiological and technical challenges



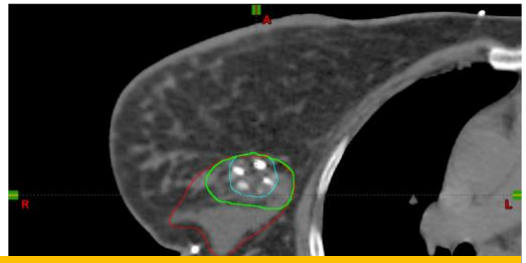
Lischalk JW et al, Adv Radiat Oncol 2018

Trials SABR in breast patients (in progress)

Name of study	Estimated number to be enrolled	Inclusion	Primary endpoints	SABR dose
Feasibility Study of Stereotactic Body Radiotherapy for Early Breast Cancer (ARTEMIS) [21]	32	Women ≥ 70 yr with preoperative early-stage breast cancer, followed by lumpectomy at 8–12 weeks after SABR	Treatment feasibility	40 Gy in 5 fractions every other day
Single Dose Ablative Radiation Treatment for Early-Stage Breast Cancer (ABLATIVE) [22]	25	Core biopsy positive nonlobular carcinoma, with negative sentinel lymph node biopsy followed by lumpectomy 6 months after SABR	Pathological complete response	20 Gy in 1 fraction
Preoperative Single-Fraction Radiotherapy in Early Stage Breast Cancer [23]	100	Women ≥ 50 yr, biopsy proven, CT1N0, ER +ve, invasive ductal, or DCIS, followed by lumpectomy 8–12 weeks after SABR	Rate of pathological response at time of surgery	21 Gy in 1 fraction
Stereotactic Image-Guided Neoadjuvant Ablative Radiation Then Lumpectomy (SIGNAL) [24]	120	Postmenopausal women ≥ 55 yr, ≤3 cm, ER +ve, clinically node negative, invasive ductal carcinoma, followed by lumpectomy 6–8 weeks after SABR	Toxicity resulting from radiation	21 Gy in 1 fraction
Preoperative Stereotactic Ablative Body Radiotherapy (SABR) for Early-Stage Breast Cancer [25]	40	Women ≥ 50 yr, invasive adenocarcinoma, ≤2 cm, followed by lumpectomy 6 weeks after SABR	Rate of pathological complete response	3 fractions

Barry A et al, Int J Breast Cancer 2018

OBS and tumour bed localization



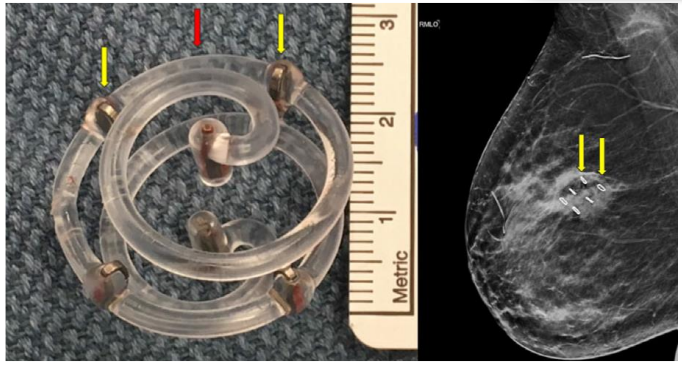
Tissue rearrangement can alter the original position

Radiation practice patterns among US ROs

Collaborating surgeons routinely (33.1%) or occasionally (38.3%) place clips at the lumpectomy cavity

38.7% of ROs delivers a boost for patients with OBS only if clips have been placed, 34.6% uses boost regardless of clips placement

Thomas K et al, Pract Radiat Oncol 2014



Special device

Additional cost
Limit the ability to close the defect at the time of OBS

Wiens N et al, J Radiat Oncol 2018

Current challenges

- **Adaptation to tumour biology**

Efforts are currently under way to tailor adjuvant RT to a patient's biologic subtype. The goal is to intensify the treatment in HR patients, and de-escalate the treatment in LR patients. Trials omitting RT in favourable groups indicate that improved techniques to selects appropriate patients for treatment de-escalation are needed

Several investigators have suggested utilization of gene signature and biomarkers to predict the benefit of RT in both early and advanced stage breast cancer. Radiomics and Radiogenomics aim to correlate imaging phenotypes with underlying genes, mutations, and expression patterns

Radiomics and radiogenomics

Radiomics

An emerging translational field of research, aiming to extract mineable high-dimensional data from clinical images, containing information that reflect the underlying patho-physiology of a tissue

Imaging Genomics*:* Analysis of imaging features that predict genetic information within individual tumors (imaging-genetic biopsies)

Radiation Genomics*:* Analysis of individual genetic variations that affect the response of normal tissues to radiation therapy (prediction of radiotoxicity)

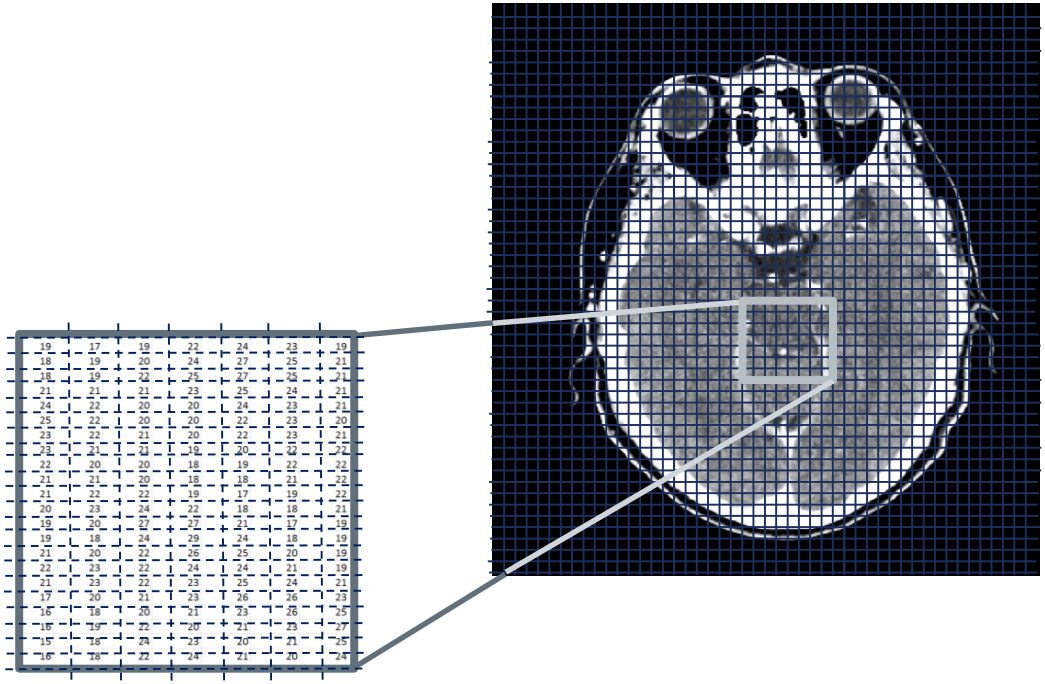
Radiogenomics

Images are not only pictures…..

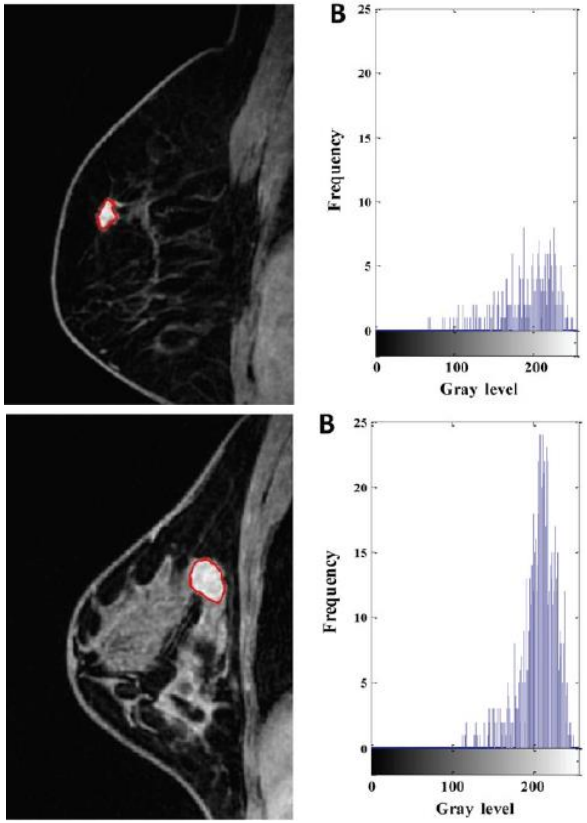
Images are not only pictures…..

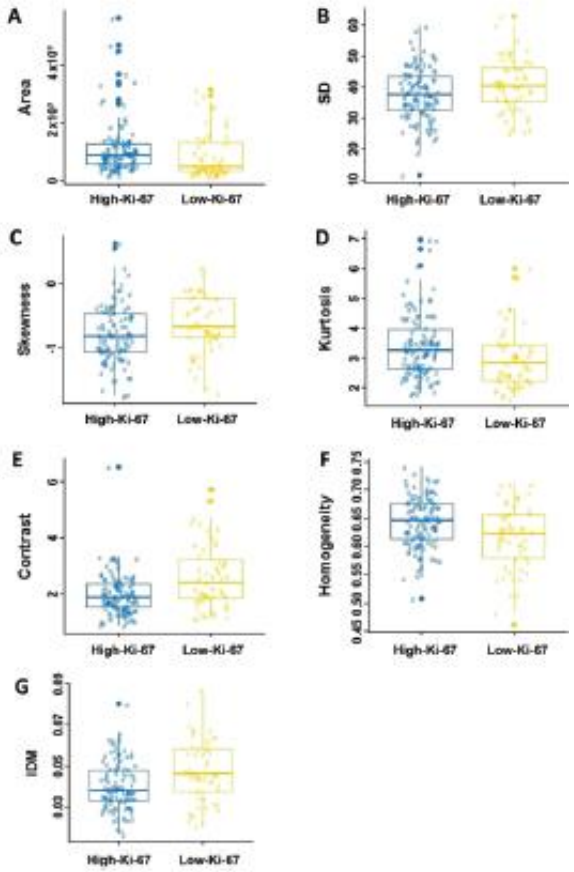
- Tumour Intensity
- Tumour Shape
- Tumour Texture
- Wavelet

each pixel contains a *number*



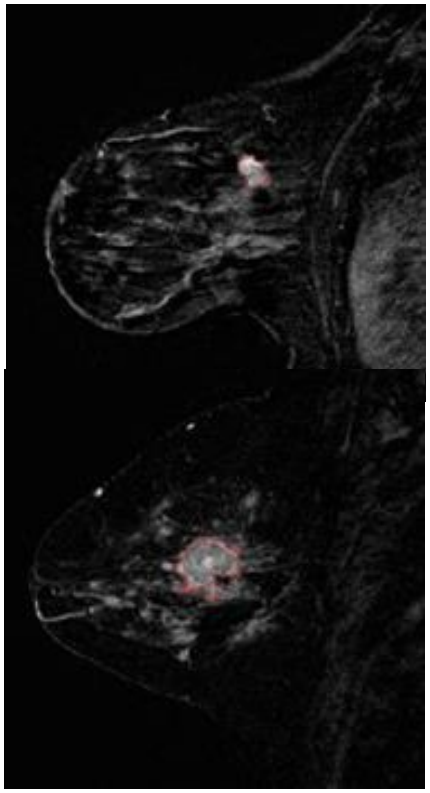
Correlation between DCE-MRI radiomics features and Ki-67 expression in invasive breast cancer





Juan MW et al, Oncol Lett 2018

Imaging and the completion of the omics paradigm in breast cancer



(a) ER positive

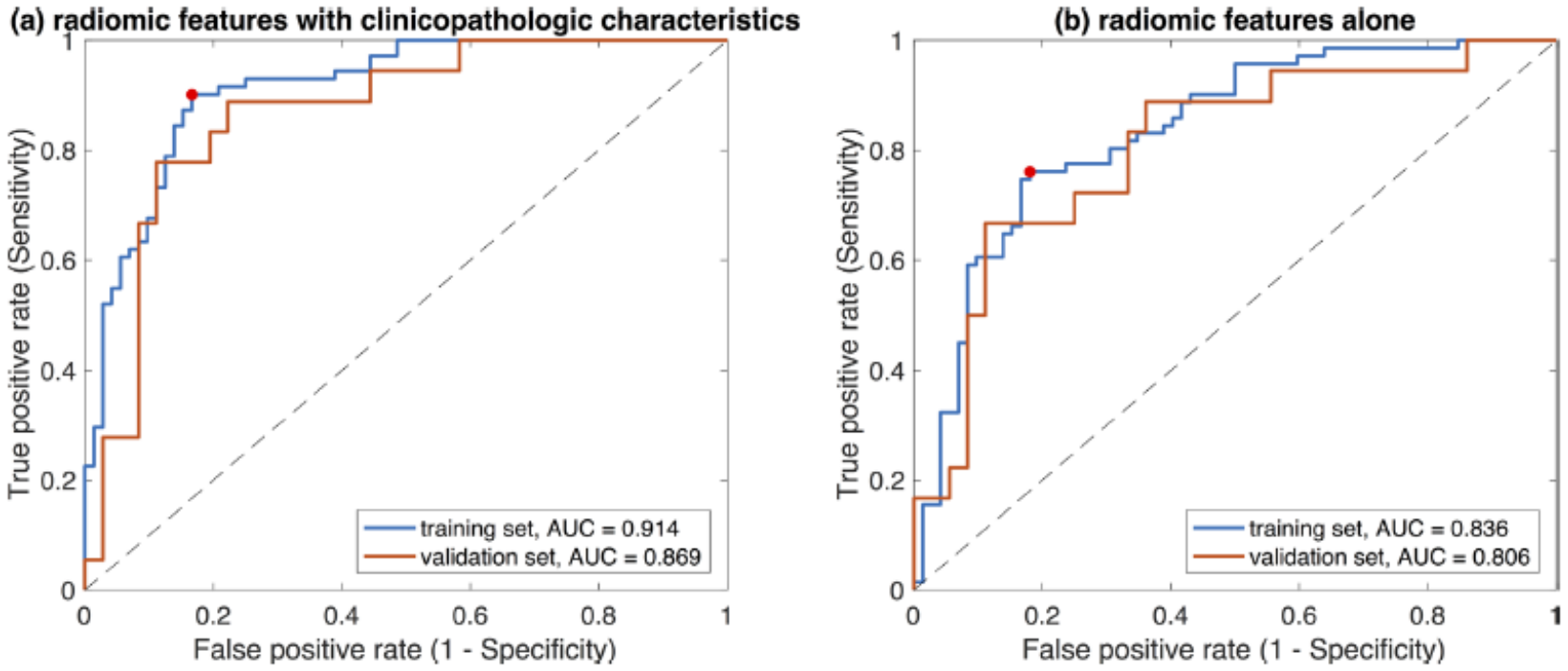
	ER-Positive Case (a)	ER-Negative Case (b)
Cancer Subtype	Luminal A	HER2-enriched
MRI CEIP Size (Effective Diameter) Range [7.8–54.0]	12.9 mm	23.8 mm
MRI CEIP Shape (Irregularity) Range [0.40–0.84]	0.452	0.602
MRI CEIP Enhancement Texture (Entropy) Range [6.00–6.59]	6.30	6.46

CEIP: Computer-Extracted Image Phenotypes

(b) ER negative

Li H t al, Radiology 2018; Pinker K et al, Radiology 2018

Preoperative Prediction of Sentinel Lymph Node Metastasis in Breast Cancer by Radiomic Signatures From Dynamic Contrast-Enhanced MRI



Liu C et al, J Magn Reson Imaging 2019

Radiomics: the bridge between medical imaging and personalized medicine

Philippe Lambin[1], Ralph T.H. Leijenaar[1], Timo M. Deist[1]*, Jurgen Peerlings[1,2], Evelyn E.C. de Jong[1], Janita van Timmeren[1], Sebastian Sanduleanu[1], Ruben T.H.M. Larue[1], Aniek J.G. Even[1], Arthur Jochems[1], Yvonka van Wijk[1], Henry Woodruff[1], Johan van Soest[3], Tim Lustberg[3], Erik Roelofs[1,3], Wouter van Elmpt[3], Andre Dekker[3], Felix M. Mottaghy[2,4], Joachim E. Wildberger[2] and Sean Walsh[1]*

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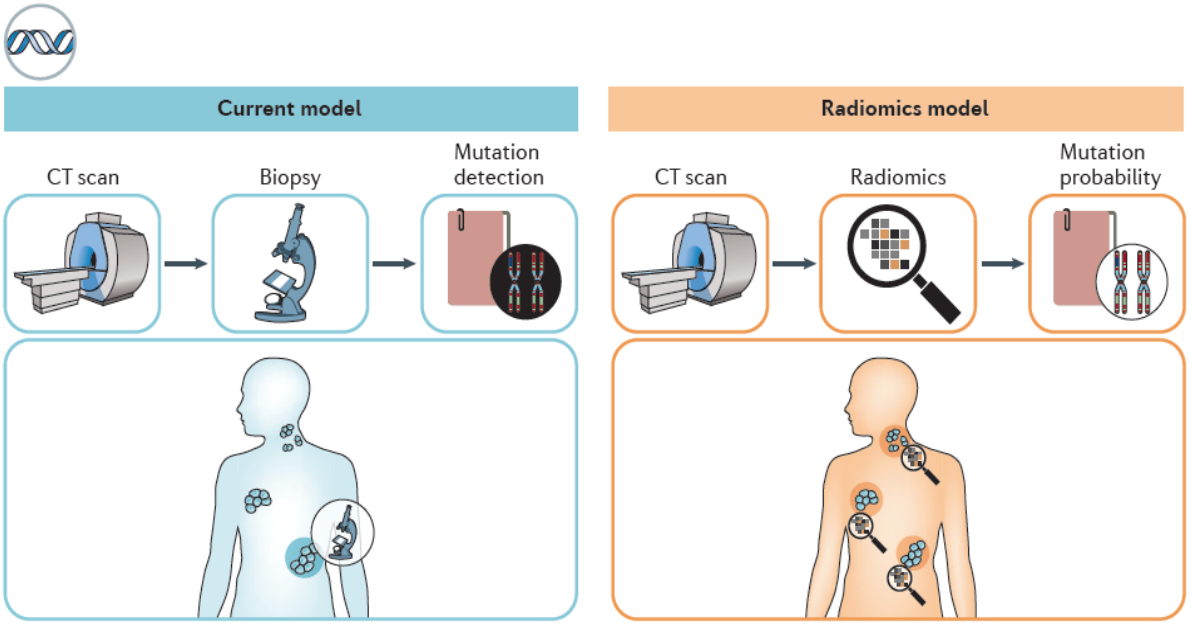
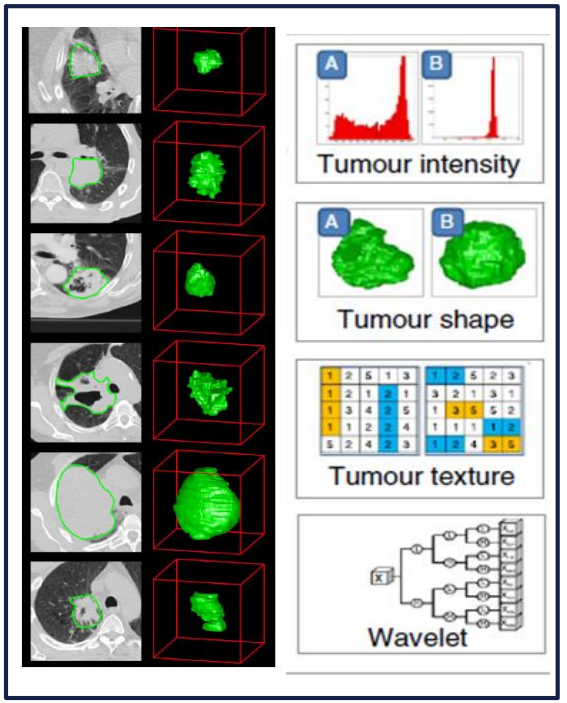
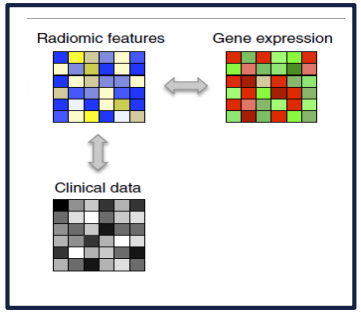






Brief Insight into Radiation Genomics

Analysis of individual genetic variations that affect the response of normal tissues to radiation (prediction of radiotoxicity)

The Problem

Adverse reactions in normal tissue after RT limit the dose that can be given to tumour cells

The Challenge

Identify individual traits that allow prediction of patients with increased risk of developing radio-toxicity

(80% of individual variation in clinical response is caused by patient-related factors)

Analysis of germline variants in patients' DNA

Analysis of radiation-induced gene expression patterns in patients' normal fibroblasts/ lymphocytes

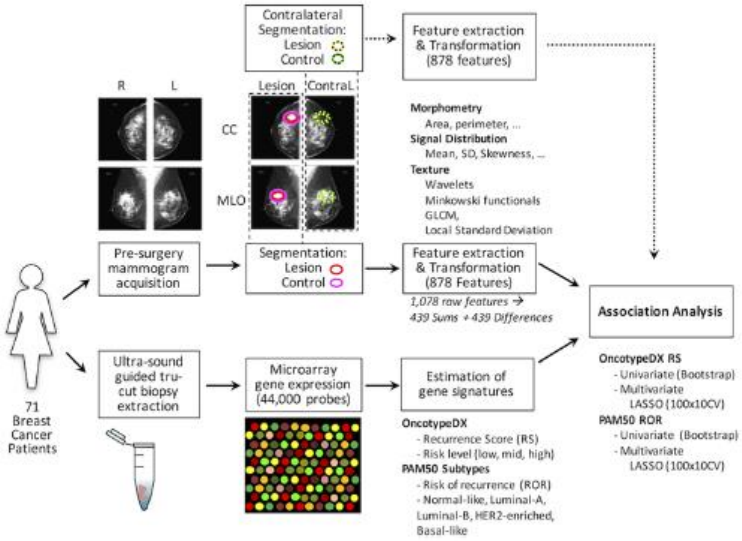
The Goal

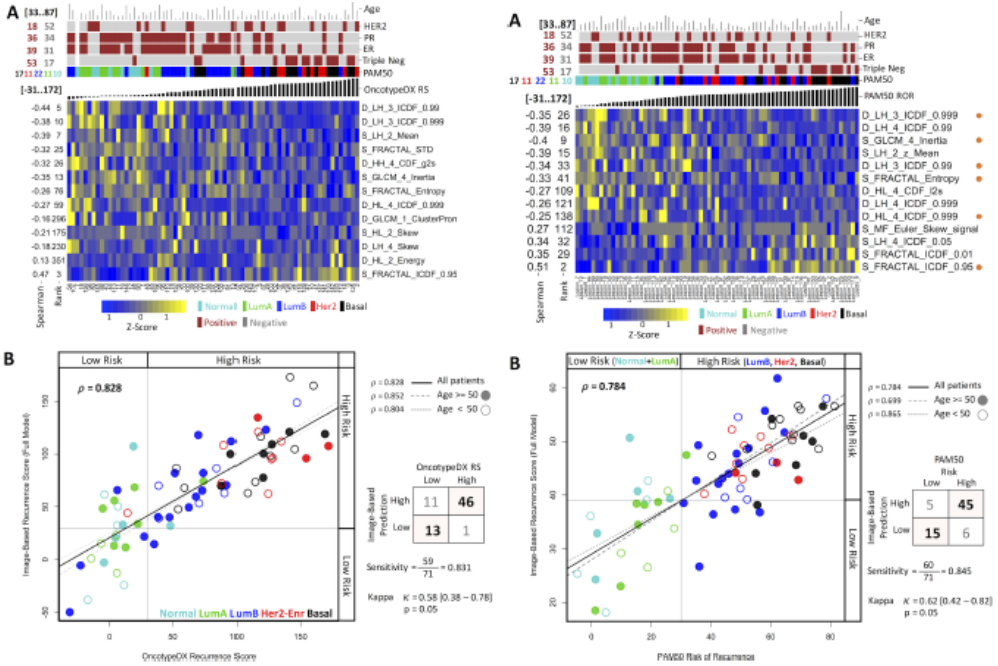
Identify germline variants and somatic epigenetic factors (transcription) modulating biological responses of normal tissues to radiation

The Plan

Establish a gene-based predictive test for normal tissue radiosensitivity

Radiogenomics analysis identifies correlations of digital mammography with clinical molecular signatures in breast cancer





Tamez-Peña JG et al, PLOS ONE 2018

Current challenges

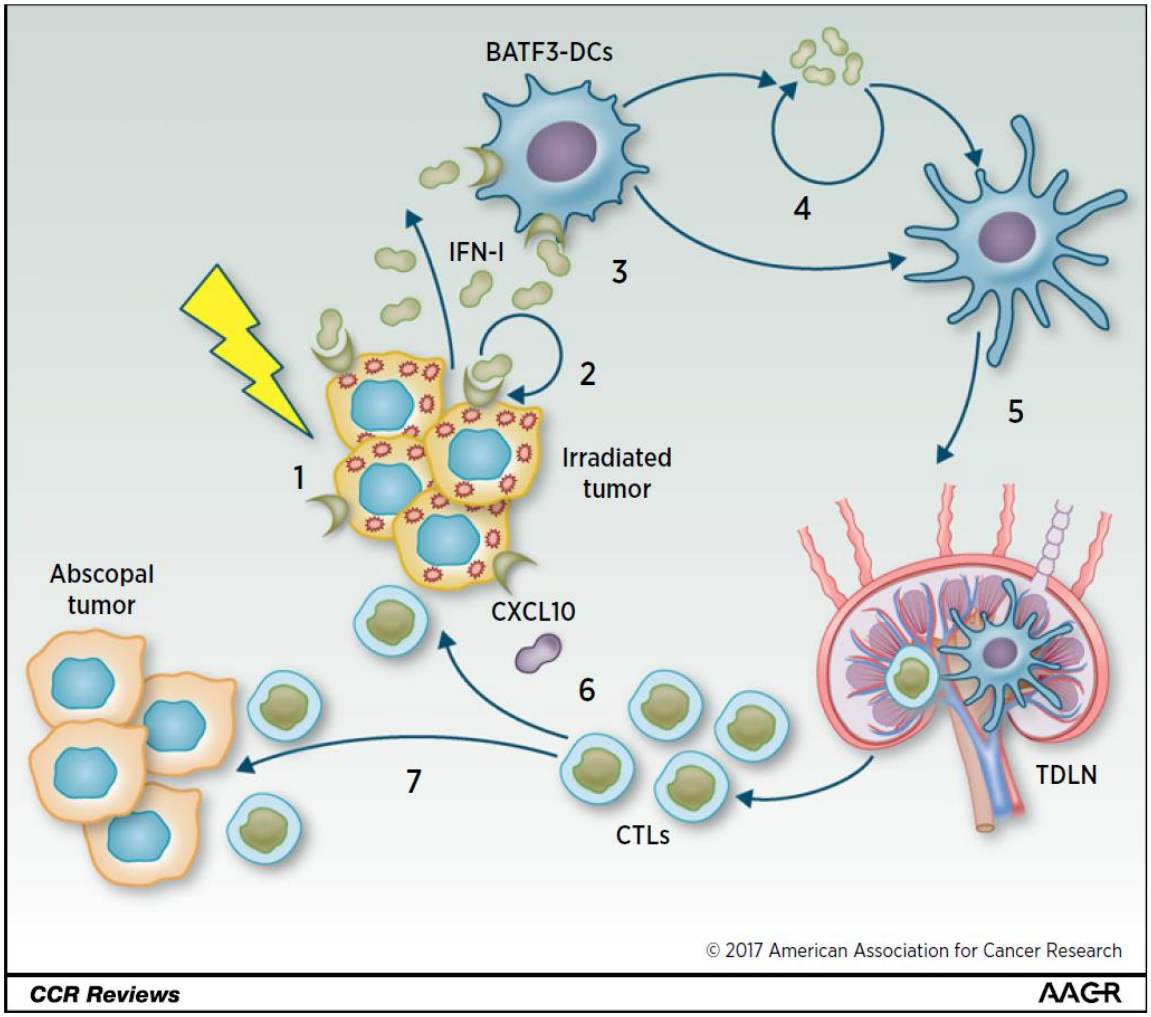
- **Integration of radiation and immunotherapy**

Radiation can potentiate the immunotherapeutic effect by causing "immunogenic cell death (ICD)", and facilitate release and cross-presentation of tumour neo-antigens, activation and priming of CTLs (cytoxic T-cell), and increased infiltration of CD8+ CTLs in the tumour microenviroment

When combined with immune checkpoint blockade, radiation is best harnessed by hypofractionated regimes (8Gyx3, or 6Gyx5), ideally in patients with limited size lesions and relatively low disease burden

Role of IFN-I in the development of therapeutic relevant tumour-specific immune responses

Radiation by itself has the potential to effectively induce the secretion of IFN-I within the tumour microenviroment



Vanpouille-Box C et al, Clin Cancer Res 2017

Trials using checkpoint blockade and RT in progress

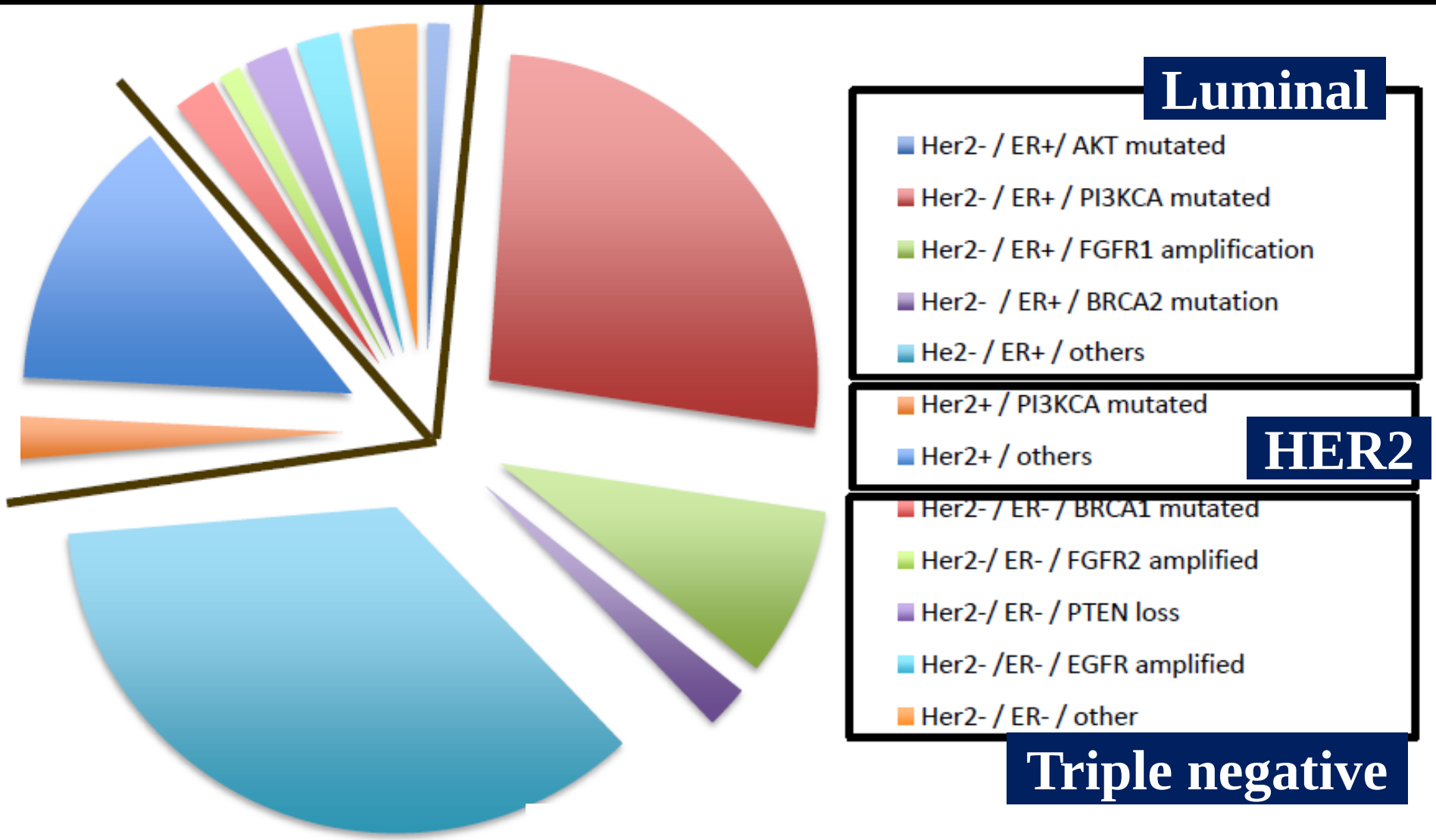
CTLA-4 inhibitors with RT			
Tremelimumab with brain irradiation	Breast cancer with brain metastases	MSKCC	Phase 2, recruiting
PD-1 and/or PD-L1 inhibitors with RT			
Pembrolizumab and 6 Gy × 5 fractions of irradiation within 5-7 d	Metastatic TNBC	MSKCC	Phase 2, recruiting
Pembrolizumab and hypofractionated RT	Metastatic breast cancer	Abramson Cancer Center of University of Pennsylvania	Phase 1, recruiting
Pembrolizumab and 20 Gy × 1 fraction (SABR)	Oligometastatic breast cancer	Peter MacCallum Cancer Centre, Australia	Phase 1, recruiting
Durvalumab with tremelimumab and 8 Gy × 3 fractions vs 17 Gy × 1 fraction*	Metastatic breast cancer	Abramson Cancer Center of University of Pennsylvania	Phase 1, recruiting
Nivolumab given after either 20 Gy × 1 fraction, low-dose doxorubicin, cyclophosphamide, cisplatin, or no induction treatment	TNBC	Netherlands Cancer Institute	Phase 2, recruiting
Pembrolizumab and SABR*	Breast cancer	University of Chicago	Phase 1, recruiting

Hu ZI et al, Int J Radiat Oncol Biol Phys 2017; Ye JC et al, The Breast 2018

Immunoradiotherapy in BC remains an under-studied domain

Investigations that delucidate the baseline tumor profile and the response to different immunotherapy strategies can provide indications for including RT to enhance the IT effect

Molecular classification of breast cancer



Biology Adapted Radiation Therapy

Molecular subtypes of BC not only predict DM may also can improve prediction of LRR risk, and has the potential to hugely inform decision-making regarding LRR control strategies

- **Immuno-histochemistry breast cancer subtypes:**

  - Luminal A
  - Luminal B
  - HER -2
  - Basal-like(Triple Negative)

Something of new?

- Luminal A
  - High radiosensivity
  - Low LRR rate
  - Local pattern of recurrence
  - To discuss: omission of RT, dose de-escalation, PBI

- Luminal B
  - Intermediate radiosensivity
  - Intermediate LRR rate
  - True and regional pattern of recurrence
  - To discuss: dose escalation, regional node RT

Leonardi MC ….Orecchia R et al, From technological advances to biological understanding: the main steps toward high-precision RT in breast cancer. The Breast 2016
Orecchia R, Tailoring radiotherapy according to cancer subtypes, The Breast 2017

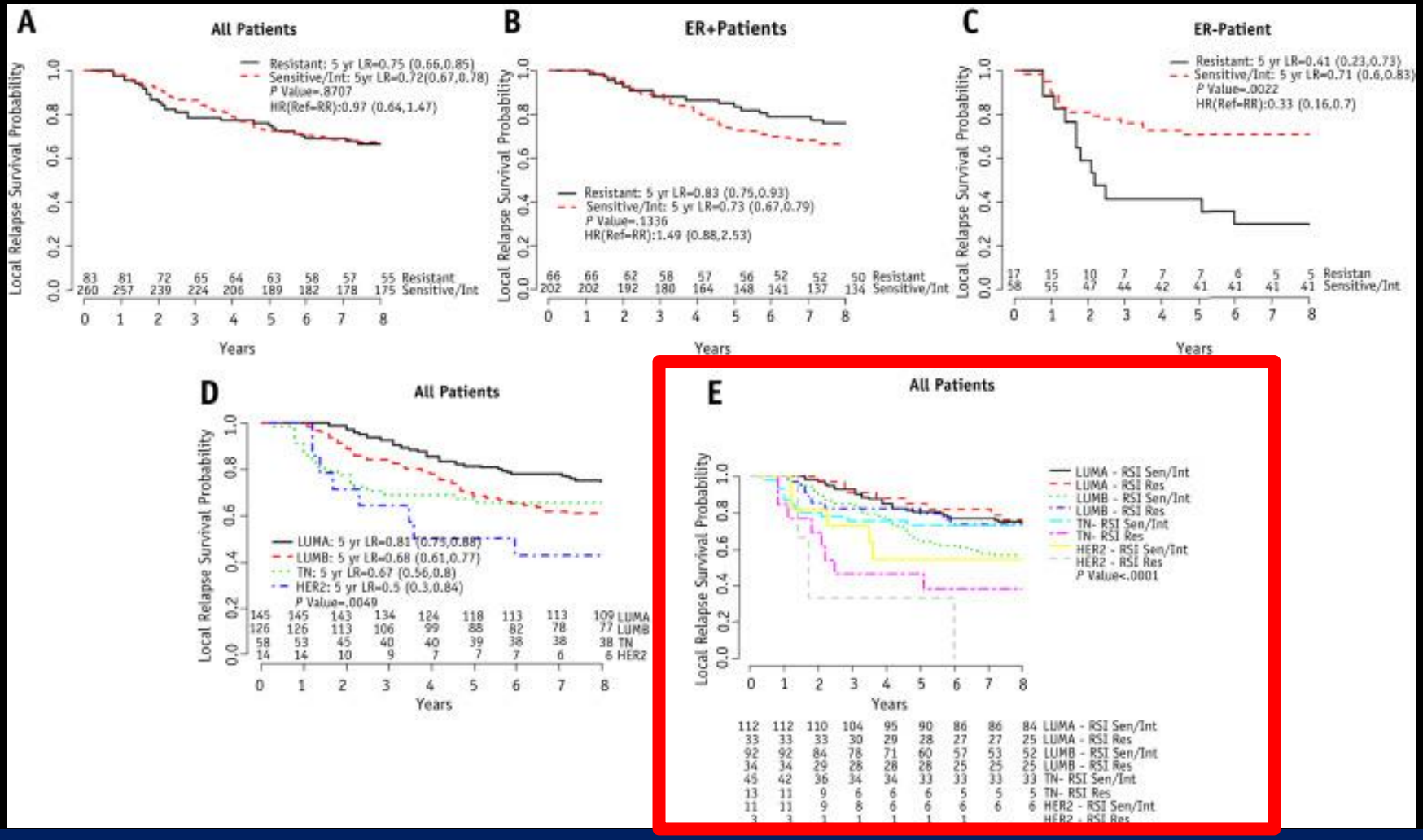
Something of new?

- HER2/neu positive
  - Low radiosensivity
  - Intermediate/high LRR rate (post/pre trastuzumab)
  - True, regional and distant pattern of recurrence
  - To discuss: dose escalation, regional node RT

- Basal-like/Triple negative
  - Very low radiosensivity
  - High LRR rate
  - True and elsewhere pattern of recurrence
  - To discuss: dose escalation, regional node RT, radiosensitizers, hypofractionaction

Leonardi MC ….Orecchia R et al, From technological advances to biological understanding: the main steps toward high-precision RT in breast cancer. The Breast 2016
Orecchia R, Tailoring radiotherapy according to cancer subtypes, The Breast 2017

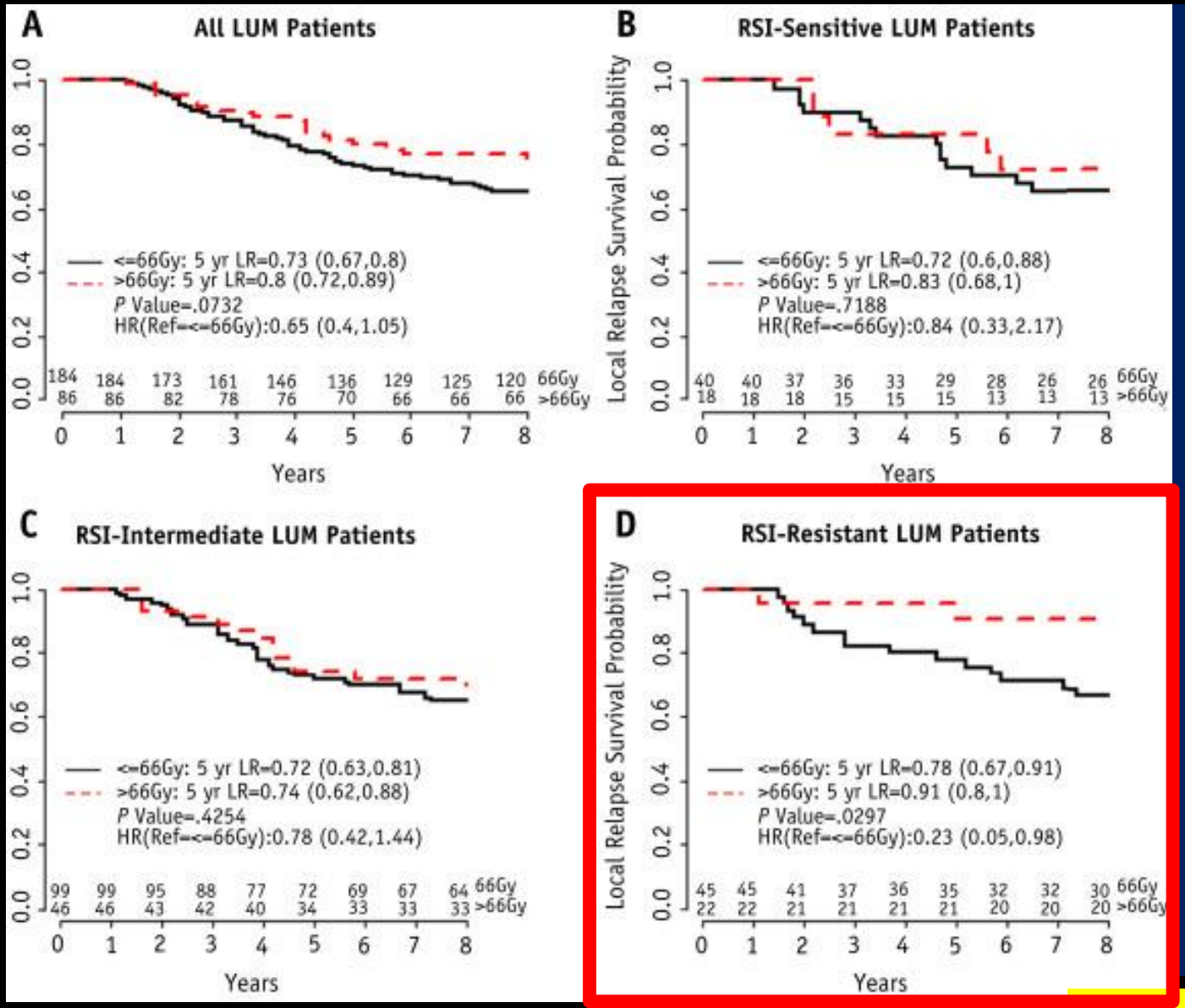
Integrating RSI and molecular subtypes



Combining RSI (RadioSensivity Index) and molecular subtype is classification of risk was further refined, specifically in ER-, HER2+ and TN patients

Torres-Roca JF et al, IJROBP 2015

Integrating RSI and molecular subtypes



(D) Higher RT dose (≤66 Gy versus >66 Gy) reduced the risk of LR for RSI-Resistant patients (P=0.02)

Torres-Roca JF et al, IJROBP 2015

Il “mondo reale”

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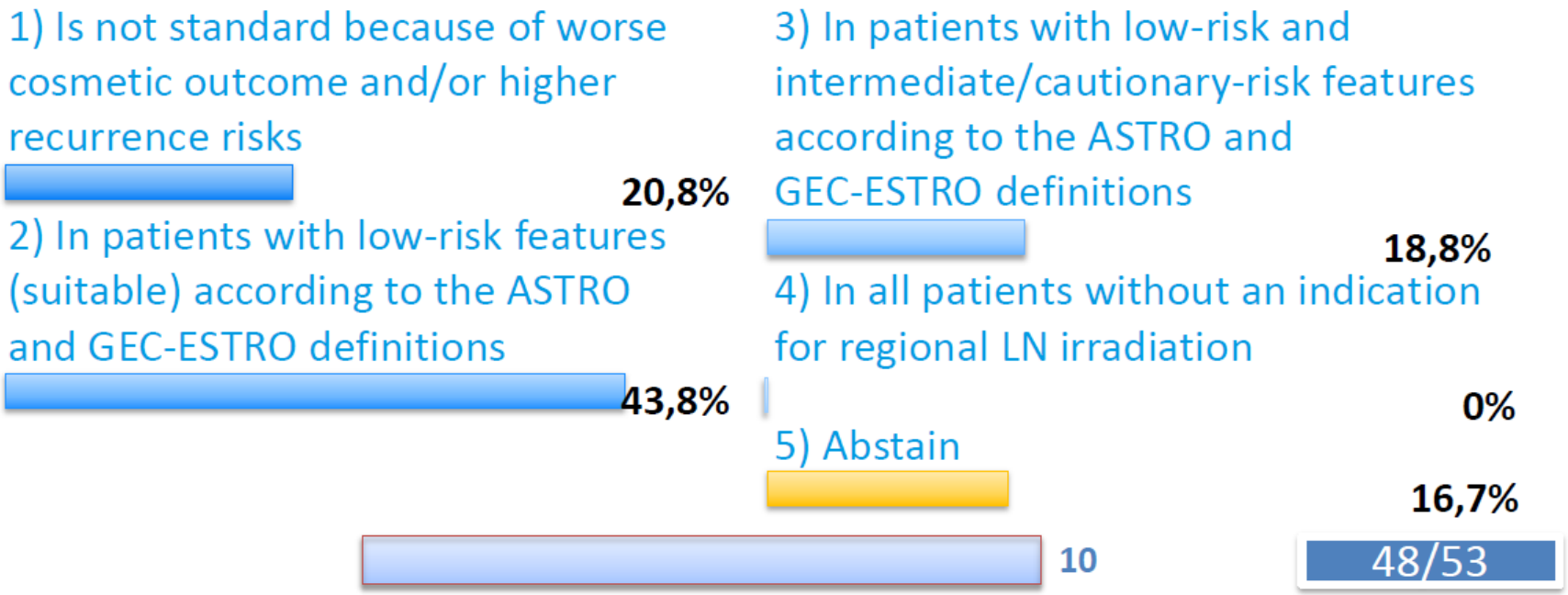
(Accelerated) Partial Breast Irradiation

34.

Based on the data of the published/recently presented trials, (A)PBI can be considered in what patient populations:



Hypofractionated breast irradiation

36.

Hypofractionated irradiation is a standard of care in (breast/chest wall irradiation only):

1) For all patients except rare circumstances like re-irradiation **52,1%**

2) Following BCS only, age > 50 years only **4,2%**

3) Following BCS only, all ages **14,6%**

4) Following BCS and mastectomy, age > 50 years only **8,3%**

5) Abstain **20,8%**

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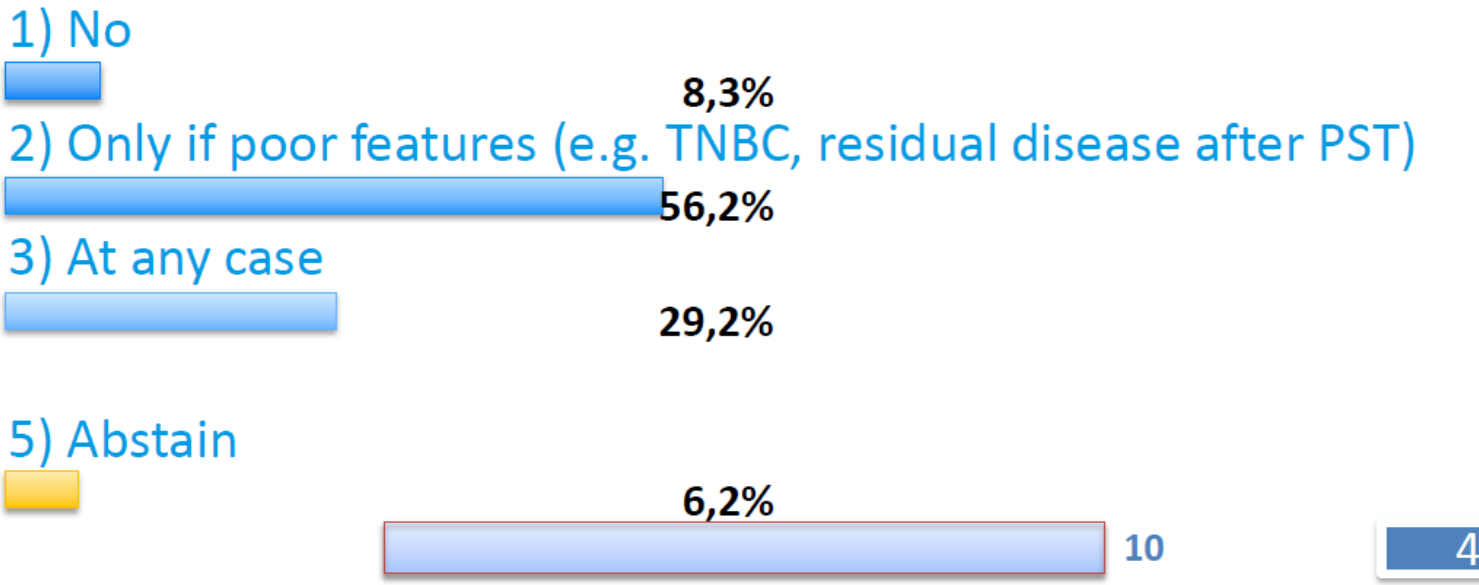
Regional node irradiation

Following breast conserving surgery, radiation should include regional nodes

38.

If 1-3 nodes are positive:



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Regional node irradiation

Following breast conserving surgery, radiation should include regional nodes

39.

If 4 or more nodes are positive:

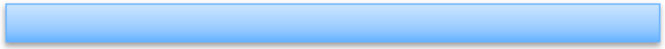
1) No

2,1%

2) Only if poor features (e.g. TNBC, residual disease after PST)

2,1%

3) At any case



93,8%

5) Abstain

2,1%

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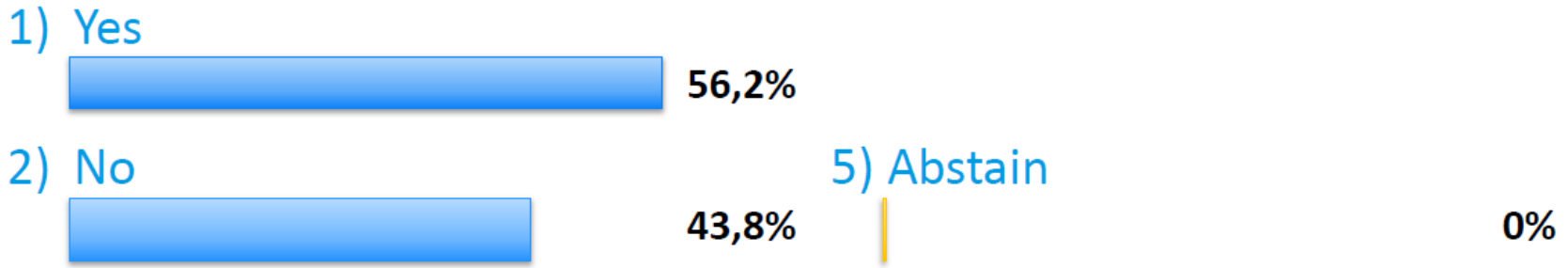
Radiation therapy: after mastectomy

Should post mastectomy RT (chest wall & regional nodes) be standard for patients with:

40.

pT3 pN0?



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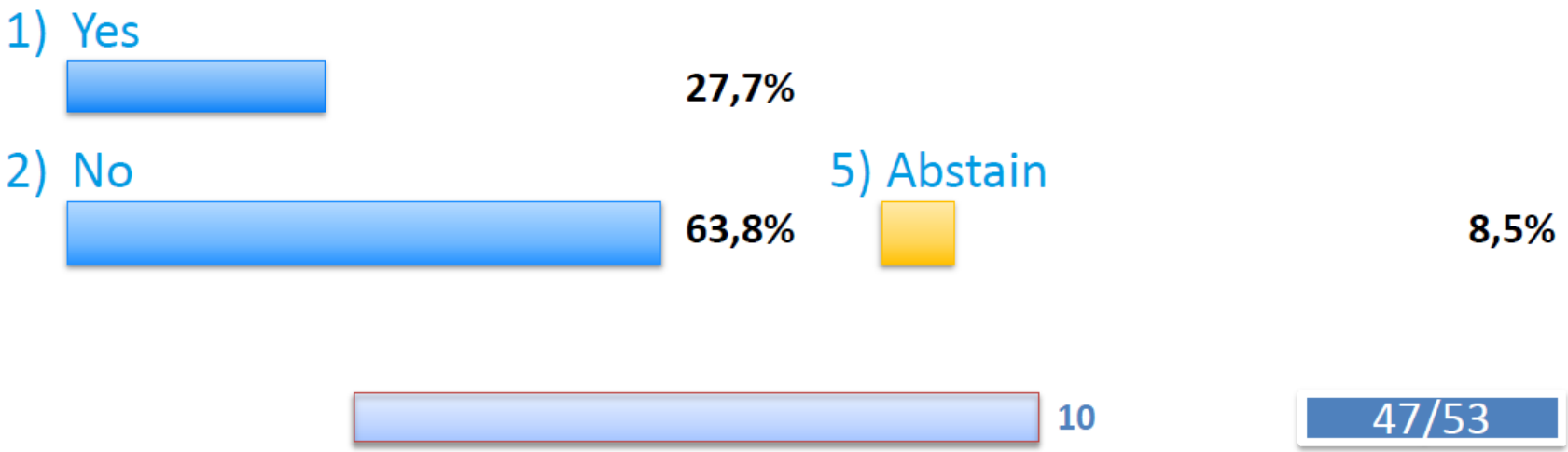
Radiation therapy: after mastectomy

Should post mastectomy RT (chest wall & regional nodes) be standard for patients with:

41.

pT2 pN0 with bad features only?

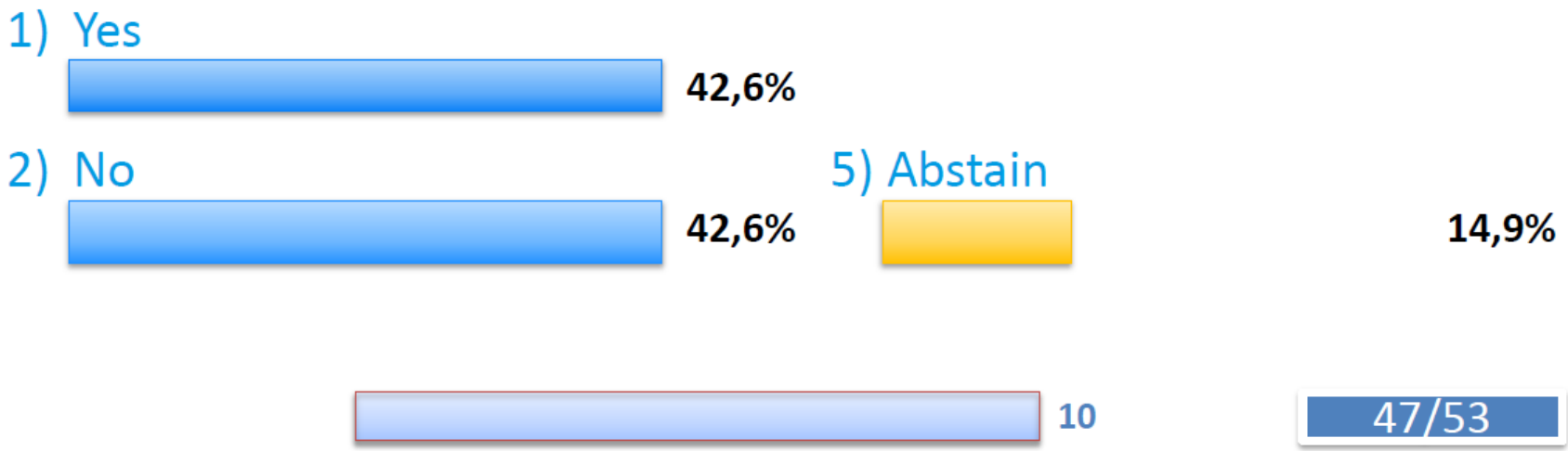


Radiation therapy: after mastectomy

Should post mastectomy RT (chest wall & regional nodes) be standard for patients with:

42.

N+ 1 to 3, ER+ and/or HER2+?



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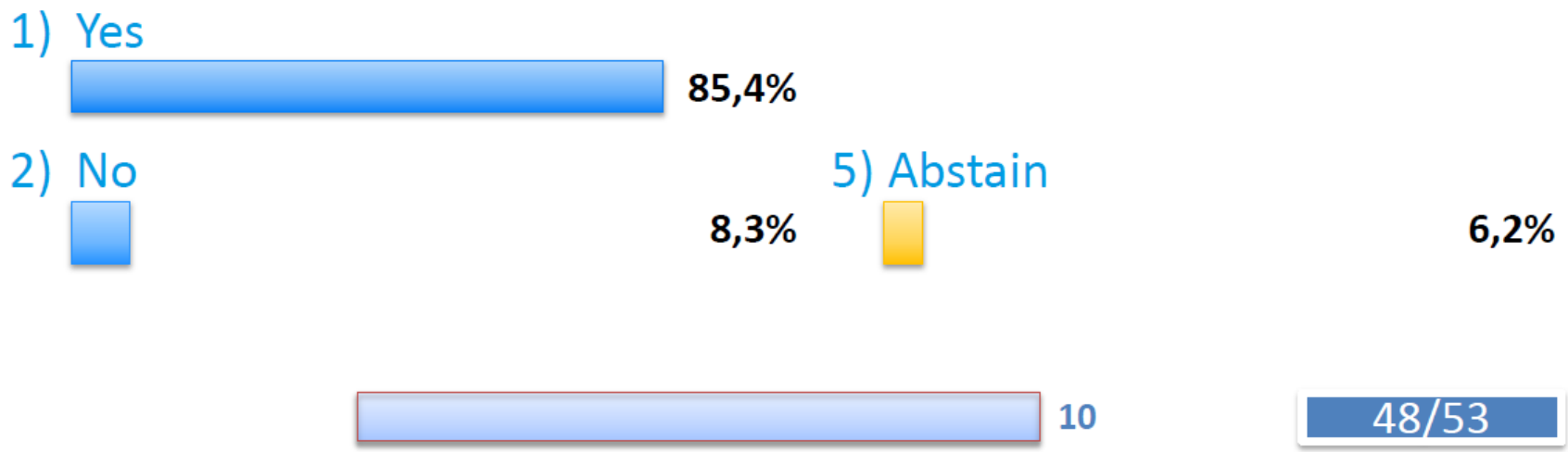
Radiation therapy: after mastectomy

Should post mastectomy RT (chest wall & regional nodes) be standard for patients with:

43.

N+ 1 to 3, with adverse features (TN)?

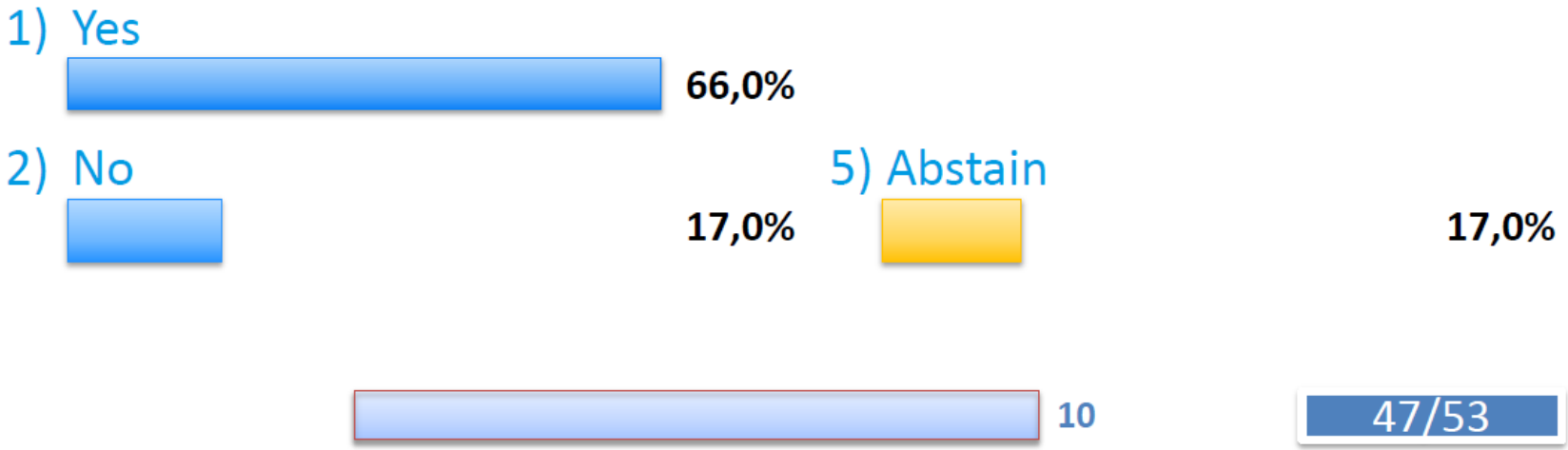


Radiation therapy: after mastectomy

Should post mastectomy RT (chest wall & regional nodes) be standard for patients (not having received PST) with:

45.

1 or 2 positive SLNs but no axillary dissection?



Radiation therapy after mastectomy and breast reconstruction

46.

In women who have undergone immediate reconstruction (IBR) :

1) PMRT indications are the as those after mastectomy without IBR

75%

2) PMRT should be limited to patients with very high-risk features only because of the increased complication risk after IBR

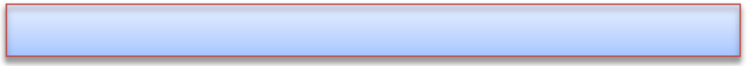
8,3%

3) PMRT in patients with implants should be limited to very high risk

4,2%

5) Abstain

12,5%



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Radiation therapy after PST

48.

Consider a healthy patient who presents with a T3N0 TNBC. Good response to PST. pCR at mastectomy with 6 cm of fibrosis; negative SLN.

1) Patient should receive PMRT because of baseline stage

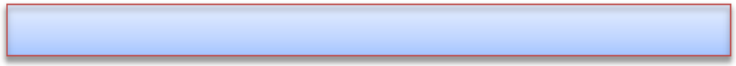
66,0%

2) Patient need not receive PMRT because of excellent clinical response

21,3%

5) Abstain

12,8%



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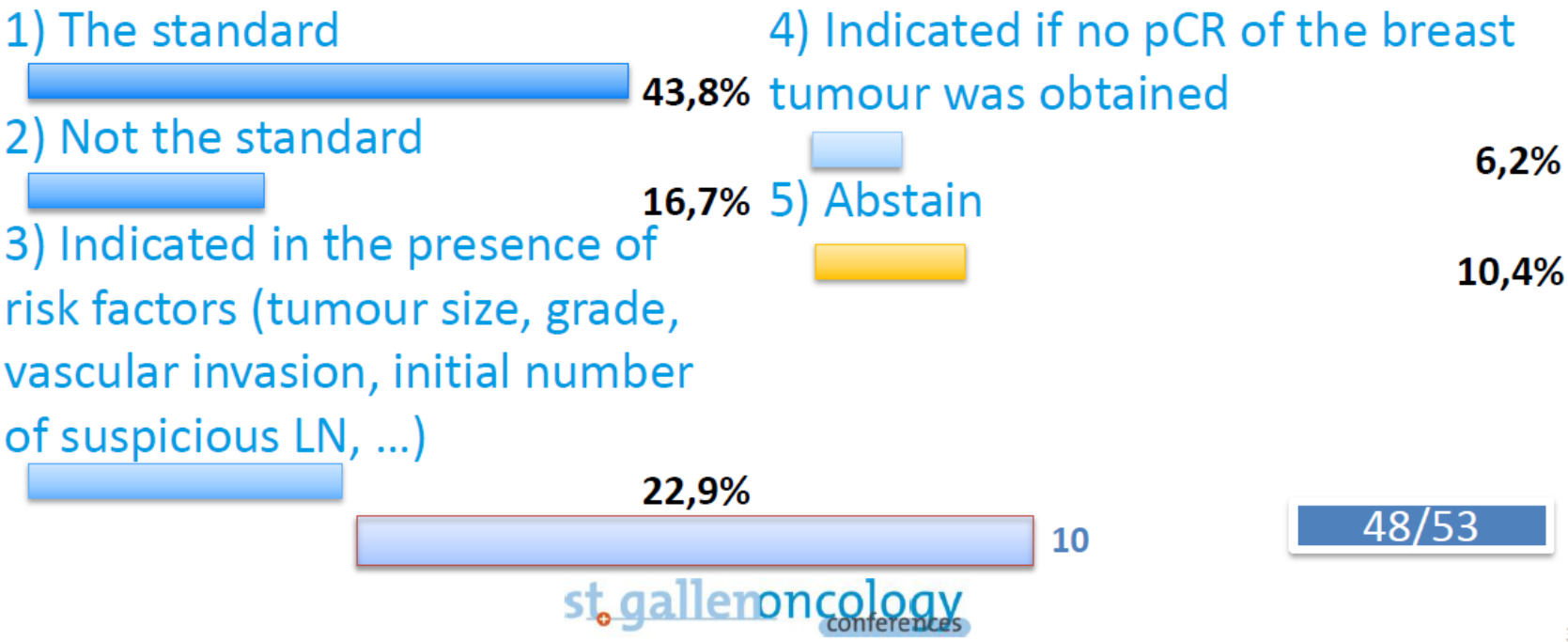
Regional lymph node irradiation following PST

32.

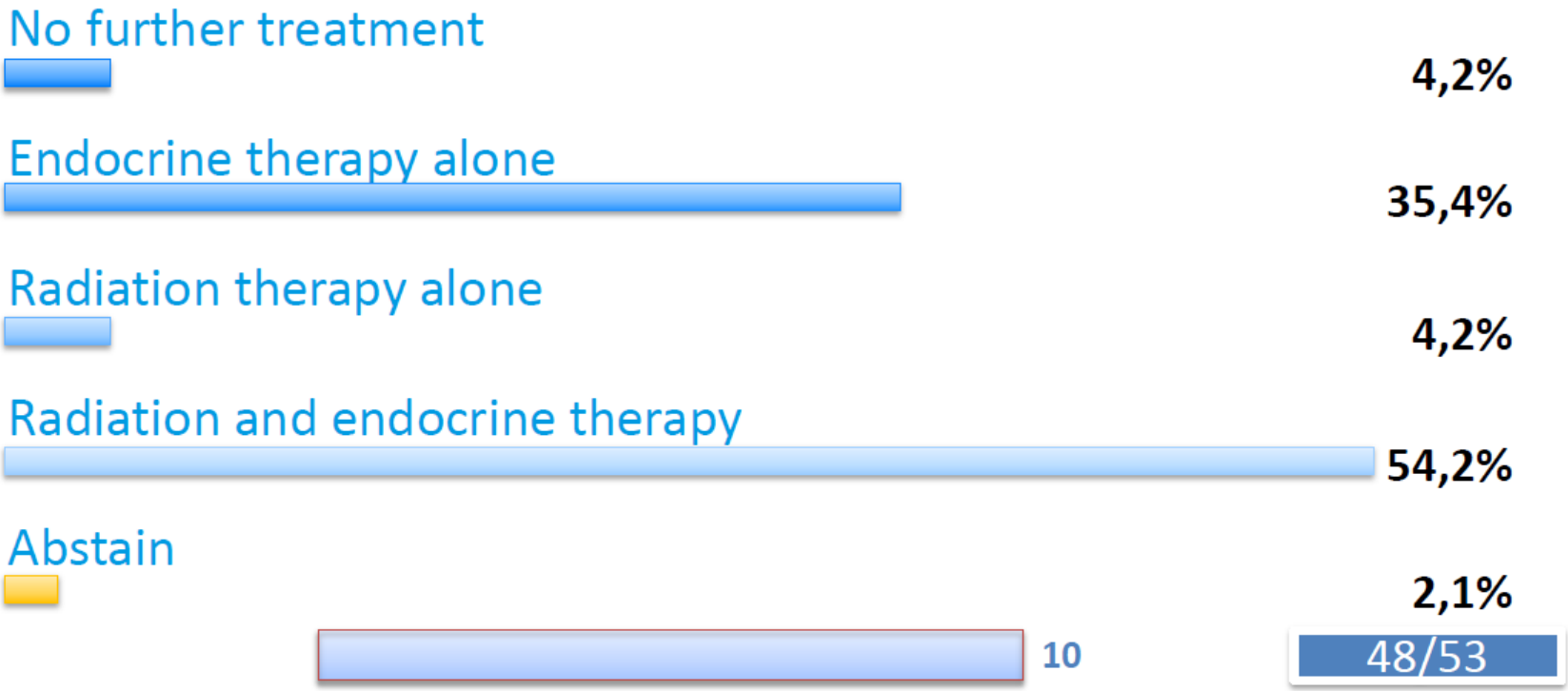
In initially cN+ patients who have a negative SLN procedure after PST, lymph node irradiation is:



Elderly patients (>70 y): radiation

49.

The preferred treatment after BCS for stage 1 ER+ disease (screening detected) in a healthy 70 year old woman is:



Grazie della pazienza !!!!!

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