



Rodrigo de Moraes Hanriot

- Membro Internacional das Sociedades Americana (ASTRO) e Européia (ESTRO) de Radioterapia
- Membro Internacional da Sociedade de Radioterapia Intraoperatória (ISIORT)
- Diretor do Departamento de Radioterapia do Hospital Alemão Oswaldo Cruz



**31 MAIO
A 2 JUN
2018**

XIX CONGRESSO SUL-BRASILEIRO
DE GINECOLOGIA E OBSTETRÍCIA
IV JORNADA SUL-BRASILEIRA
DE MASTOLOGIA
CENTROSUL | FLORIANÓPOLIS | SC



Hipofracionamento - Novo Padrão de Radioterapia em Axila Positiva ou Negativa?

Rodrigo Hanriot

Radio-oncologia - Hospital Alemão Oswaldo Cruz

“Declaro que não há conflito de interesses relacionados com esta apresentação”

Em acordo com as normas do Conselho Federal de Medicina (número 1595/2000) e de Vigilância Sanitária RDC 102/2000

Radioterapia hipofracionada X convencional

Considerar:

Toxicidade aguda

Toxicidade tardia

Cosmesis

Controle loco-regional

Sobrevida câncer específica

Sobrevida global

Custo-efetividade

Radioterapia hipofracionada X convencional

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Long-Term Results of Hypofractionated Radiation Therapy for Breast Cancer

Timothy J. Whelan, B.M., B.Ch., Jean-Philippe Pignol, M.D., Mark N. Levine, M.D., Jim A. Julian, Ph.D., Robert MacKenzie, M.D., Sameer Parpia, M.Sc., Wendy Shelley, M.D., Laval Grimard, M.D., Julie Bowen, M.D., Himu Lukka, M.D., Francisco Perera, M.D., Anthony Fyles, M.D., Ken Schneider, M.D., Sunil Gulavita, M.D., and Carolyn Freeman, M.D.

Prospectivo aleatorizado 1234 ptes. pT1-2pN0 após BCS+AD
Idade ≥ 18 anos, qualquer G, RE/RP/Her [J Nat Ca Inst 2002;94(15)1143-50]

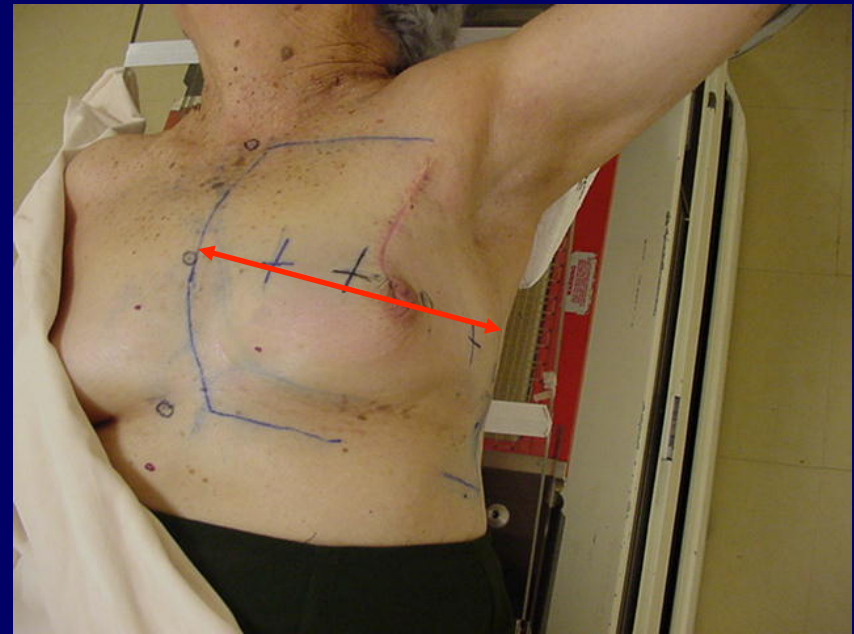
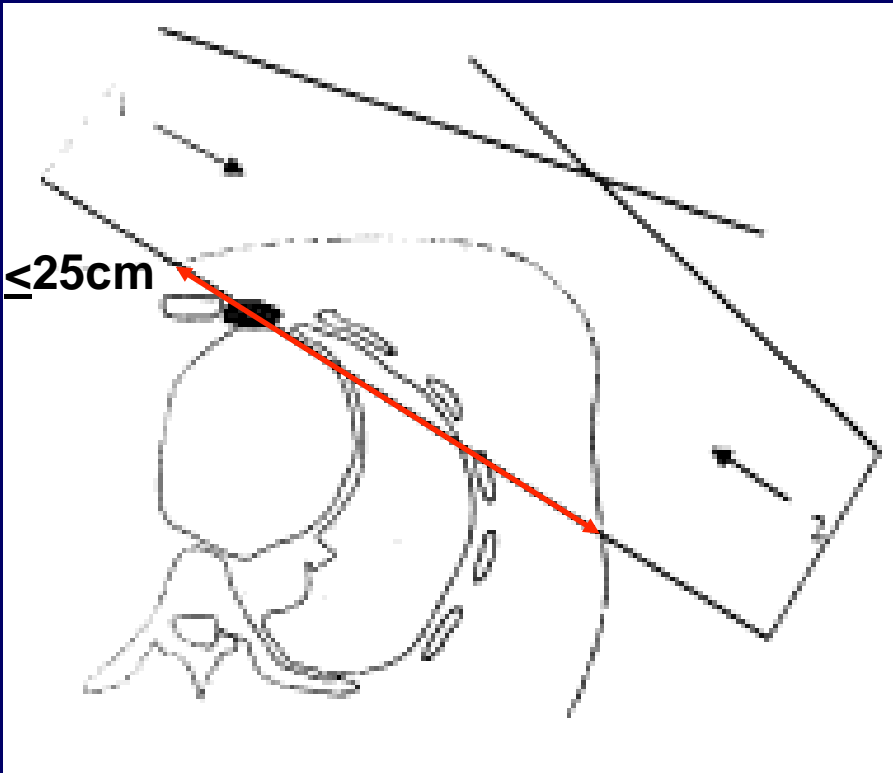
RT 16 X 2,66Gy (42,56Gy) *versus* RT 25 X 2Gy (50Gy)

NEJM após 12 anos de seguimento

N Eng J Med 2010;362:513-20

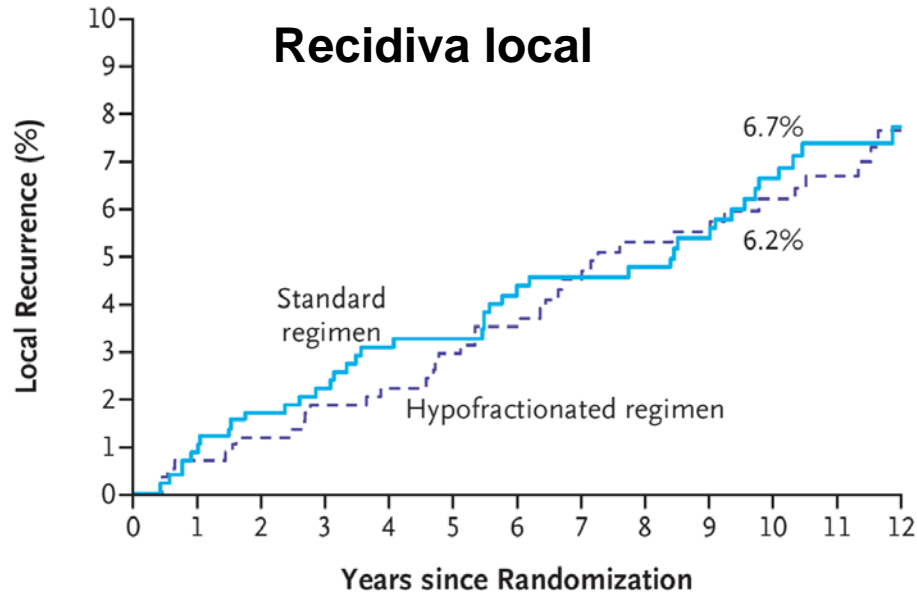
Radioterapia hipofracionada X convencional

Distância entrada-saída $\leq 25\text{cm}$

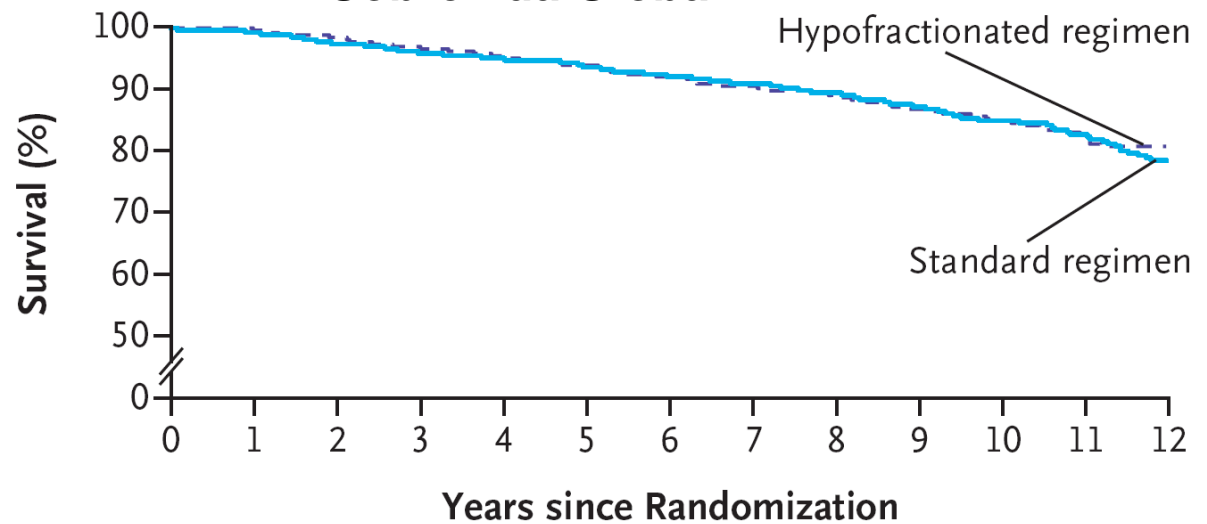


Radioterapia hipofracionada X convencional

Recidiva local



Sobrevida Global



Radioterapia hipofraccionada X convencional

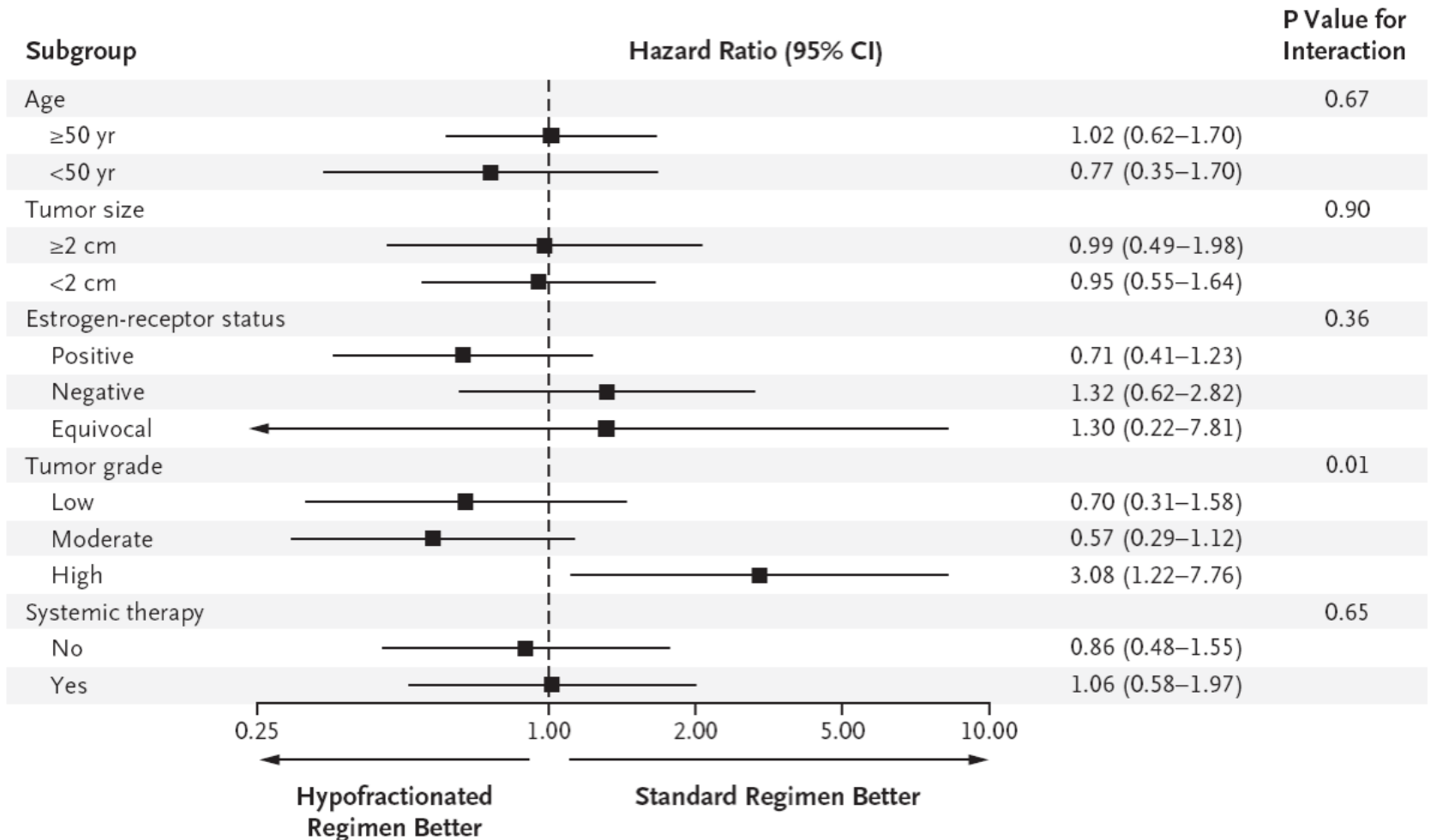


Figure 2. Hazard Ratios for Ipsilateral Recurrence of Breast Cancer in Subgroups of Patients.

Radioterapia hipofraccionada X convencional

Table 1. Late Toxic Effects of Radiation, Assessed According to the RTOG–EORTC Late Radiation Morbidity Scoring Scheme.*

Site and Grade	5 Yr		10 Yr	
	Standard Regimen (N=424)	Hypofractionated Regimen (N=449)	Standard Regimen (N=220)	Hypofractionated Regimen (N=235)
	percent of patients			
Skin				
0†	82.3	86.1	70.5	66.8
1	14.4	10.7	21.8	24.3
2	2.6	2.5	5.0	6.4
3	0.7	0.7	2.7	2.5
Subcutaneous tissue				
0‡	61.4	66.8	45.3	48.1
1	32.5	29.5	44.3	40.0
2	5.2	3.8	6.8	9.4
3	0.9	0.9	3.6	2.5

Radioterapia hipofracionada X convencional



Retorno após 01 mês da RT



Arquivo pessoal

Radioterapia hipofracionada X convencional

CLINICAL INVESTIGATION

Breast

FRACTIONATION FOR WHOLE BREAST IRRADIATION: AN AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO) EVIDENCE-BASED GUIDELINE

BENJAMIN D. SMITH, M.D.,* SOREN M. BENTZEN, PH.D., D.Sc.,[†] CANDACE R. CORREA, M.D.,[‡]
CAROL A. HAHN, M.D.,[§] PATRICIA H. HARDENBERGH, M.D.,[¶] GEOFFREY S. IBBOTT, PH.D.,^{||}
BERYL MCCORMICK, M.D., FACR.,[#] JULIE R. MCQUEEN, CHES., RHED.,** LORI J. PIERCE, M.D.,^{††}
SIMON N. POWELL, M.D., PH.D.,[#] ABRAM RECHT, M.D.,^{§§} ALPHONSE G. TAGHIAN, M.D., PH.D.,^{¶¶}
FRANK A. VICINI, M.D., FACR.,^{|||} JULIA R. WHITE, M.D.,^{##} AND BRUCE G. HAFFTY, M.D.***

Table 1. Evidence supports the equivalence of hypofractionated whole breast irradiation with conventionally fractionated whole breast irradiation for patients who satisfy all of these criteria*

1. Patient is 50 years or older at diagnosis.
2. Pathologic stage is T1–2 N0 and patient has been treated with breast- conserving surgery.
3. Patient has not been treated with systemic chemotherapy.
4. Within the breast along the central axis, the minimum dose is no less than 93% and maximum dose is no greater than 107% of the prescription dose ($\pm 7\%$) (as calculated with 2-dimensional treatment planning without heterogeneity corrections).

Radioterapia hipofracionada X convencional



The UK Standardisation of Breast Radiotherapy (START) trials of radiotherapy hypofractionation for treatment of early breast cancer: 10-year follow-up results of two randomised controlled trials

Joanne S Haviland, J Roger Owen, John A Dewar, Rajiv K Agrawal, Jane Barrett, Peter J Barrett-Lee, H Jane Dobbs, Penelope Hopwood, Pat A Lawton, Brian J Magee, Judith Mills, Sandra Simmons, Mark A Sydenham, Karen Venables, Judith M Bliss, John R Yarnold*, on behalf of the START Trialists' Group†*

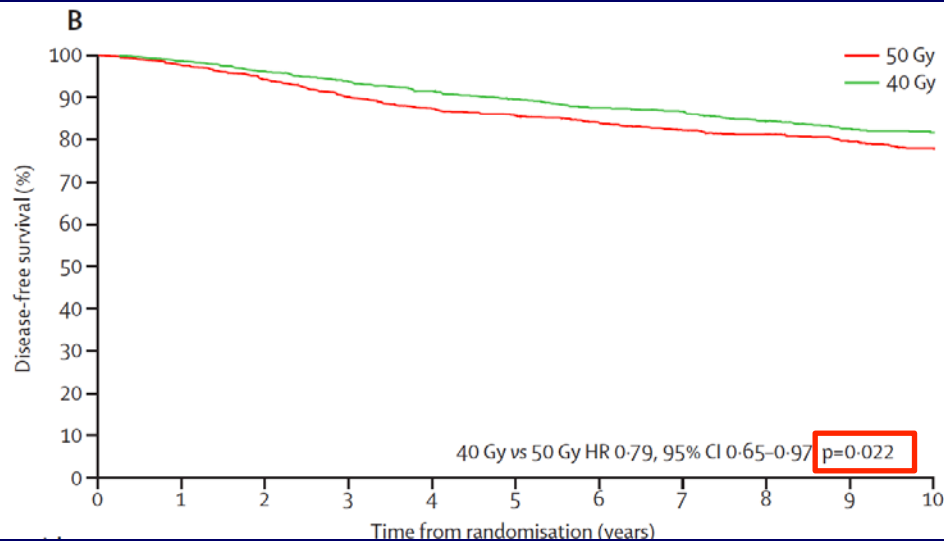
Prospectivo RT 50Gy@25 frações ou 40Gy@15 frações para pT1-3pN0-1 após BCS (92%) ou mastectomia (8%), sendo destas 7,5% com irradiação da drenagem - START B

Seguimento em 10 anos sem diferenças entre 50Gy ou 40Gy*

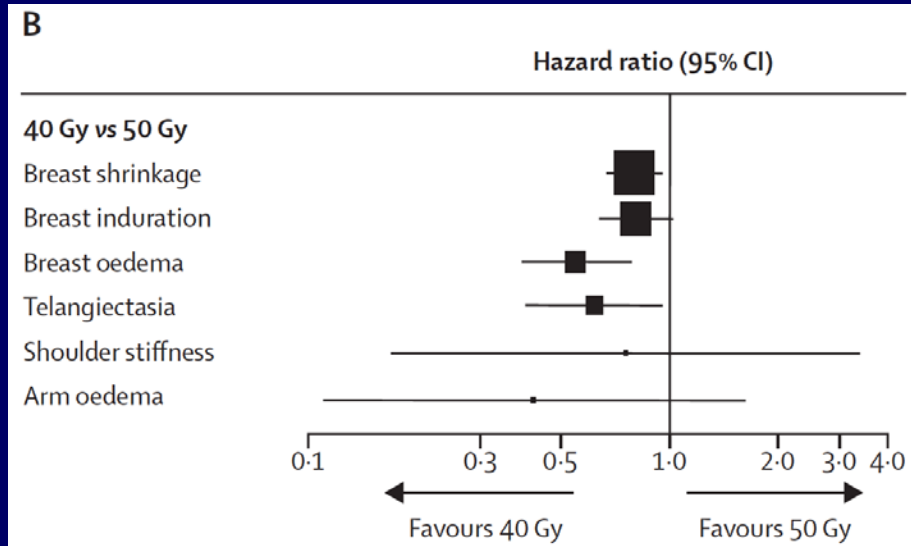
* tendência a maior SLD em hipofr.

Radioterapia hipofracionada X convencional

SLD no START B



Toxicidade tardia (A e B)



Radioterapia hipofraccionada X convencional

	START-A				START-B		
	50 Gy (n=749)	41.6 Gy (n=750)	39 Gy (n=737)	Total (n=2236)	50 Gy (n=1105)	40 Gy (n=1110)	Total (n=2215)
Symptomatic rib fracture*							
Reported	5 (0.7%)	8 (1.1%)	9 (1.2%)	22 (1.0%)	17 (1.5%)	24 (2.2%)	41 (1.9%)
Confirmed†	0	0	1 (0.1%)	1 (<0.1%)	3 (0.3%)	3 (0.3%)	6 (0.3%)
Symptomatic lung fibrosis							
Reported	6 (0.8%)	9 (1.2%)	8 (1.1%)	23 (1.0%)	19 (1.7%)	19 (1.7%)	38 (1.7%)
Confirmed†	0	2 (0.3%)	1 (0.1%)	3 (0.1%)	2 (0.2%)	8 (0.7%)	10 (0.5%)
Ischaemic heart disease‡							
Reported	14 (1.9%)	11 (1.5%)	8 (1.1%)	33 (1.5%)	23 (2.1%)	17 (1.5%)	40 (1.8%)
Confirmed†							
Total	7 (0.9%)	5 (0.7%)	6 (0.8%)	18 (0.8%)	16 (1.4%)	8 (0.7%)	24 (1.1%)
Left sided	4 (0.5%)	1 (0.1%)	4 (0.5%)	9 (0.4%)	5 (0.5%)	4 (0.4%)	9 (0.4%)
Brachial plexopathy	0	1 (0.1%)	0	1 (<0.1%)	0	0	0

Data are n (%). *Reported cases include seven after trauma (five in START-A, two in START-B), and ten after metastases (five in START-A and five in START-B). †After imaging and further investigations. ‡26 patients in START-A and 22 in START-B had pre-existing heart disease at enrolment and were excluded.

Table 3: Incidence of other late adverse effects according to fractionation schedule

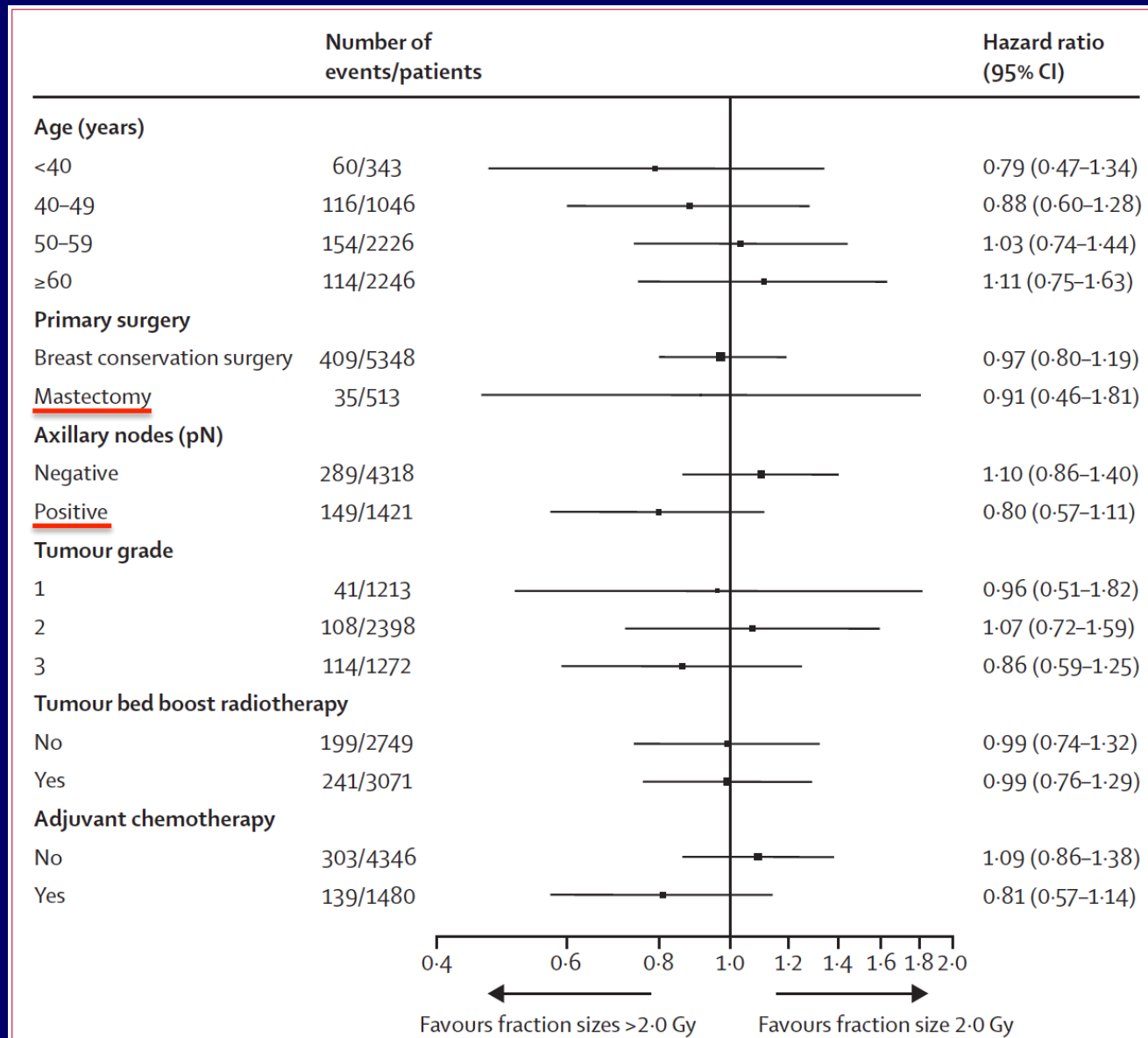
Radioterapia hipofracionada X convencional

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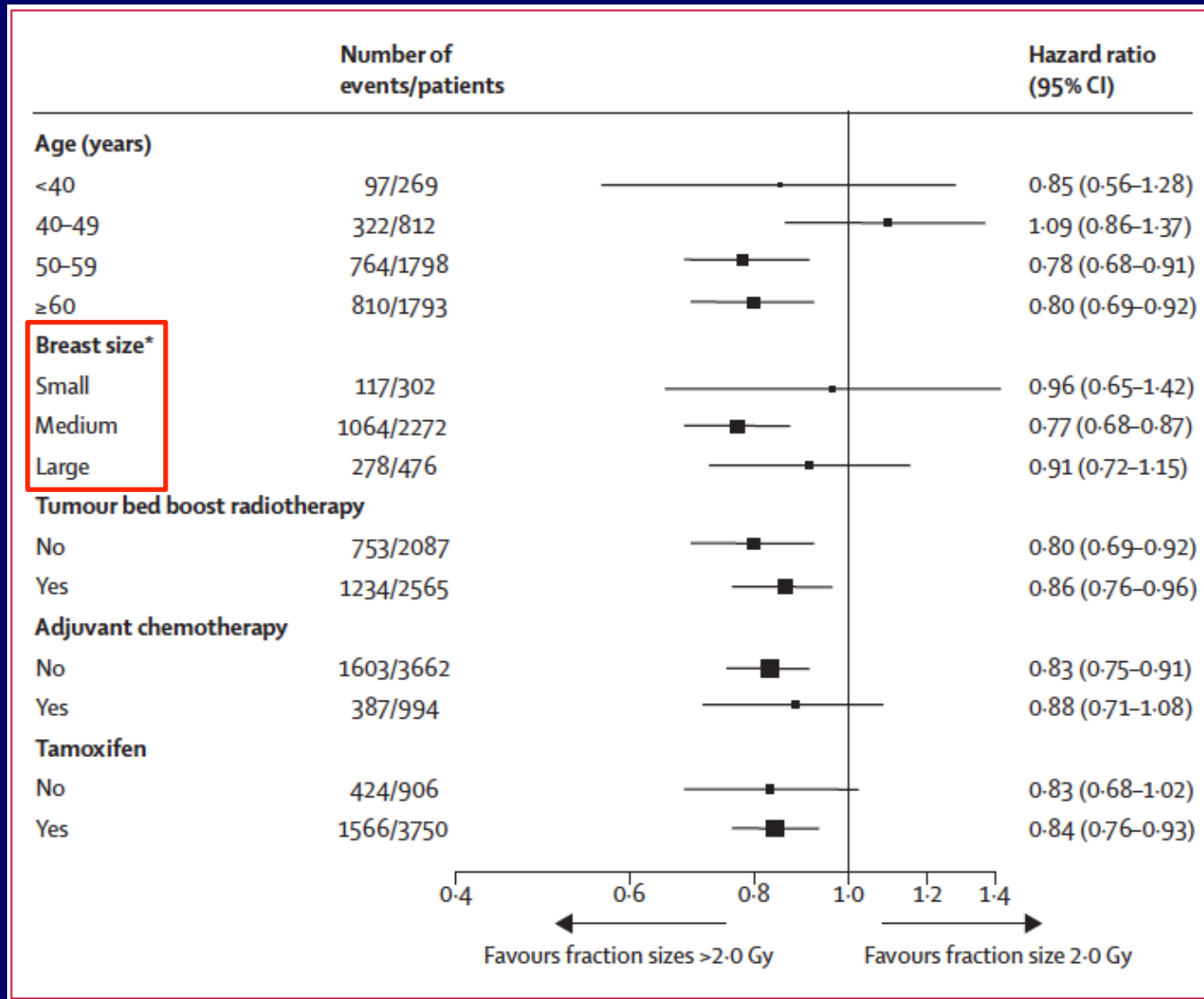
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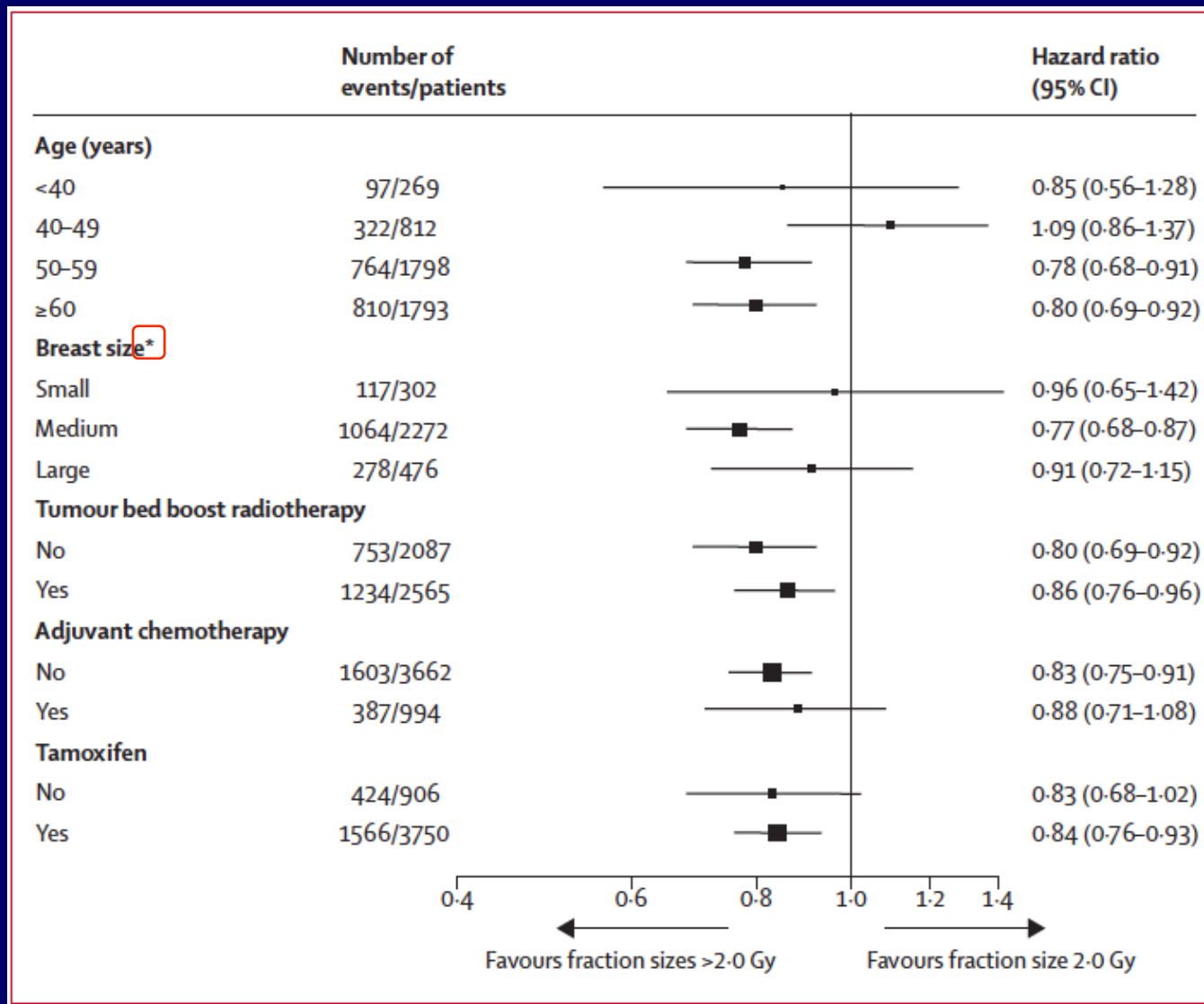
Recidiva loco-regional (A e B)



Recidiva loco-regional (A e B)



Recidiva loco-regional (A e B)

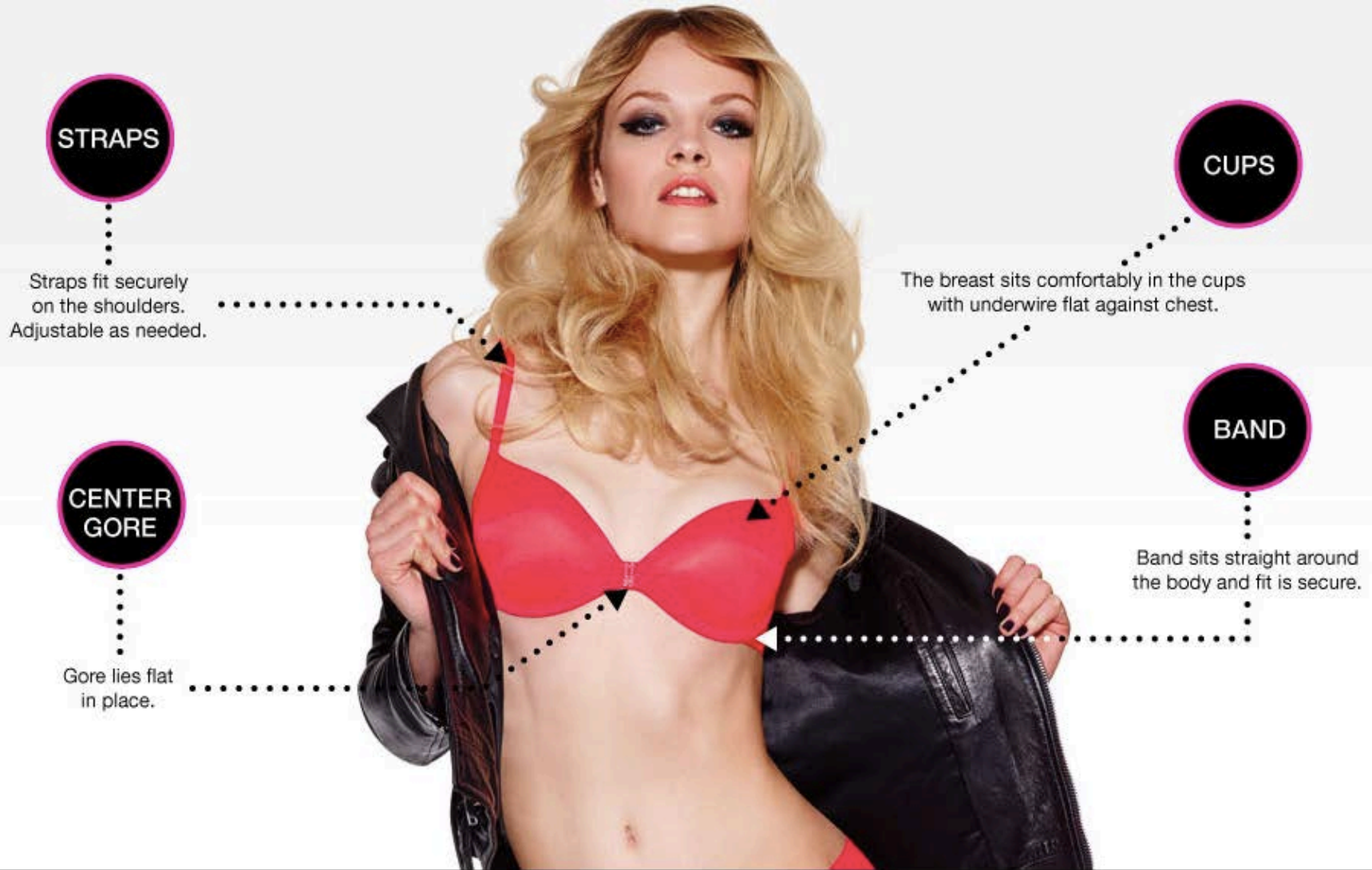


* acessado por fotografias do registro

Radioterapia hipofracionada mamas volumosas

O que é uma “mama volumosa”?

Radioterapia hipofraccionada mamas volumosas



BRA SIZE CHART & MEASURING GUIDE

Radioterapia hipofraccionada mamas volumosas

How Do You Measure Band And Cup Size?



Image: Shutterstock

Radioterapia hipofraccionada mamas volumosas

Difference In Inches – Corresponding Cup Size

- 0 ➤ *your cup size is AA*
- 1 ➤ *your cup size is A*
- 2 ➤ *your cup size is B*
- 3 ➤ *your cup size is C*
- 4 ➤ *your cup size is D*
- 5 ➤ *your cup size is E*



What is a large breast? Measuring and categorizing breast size for tangential breast radiation therapy

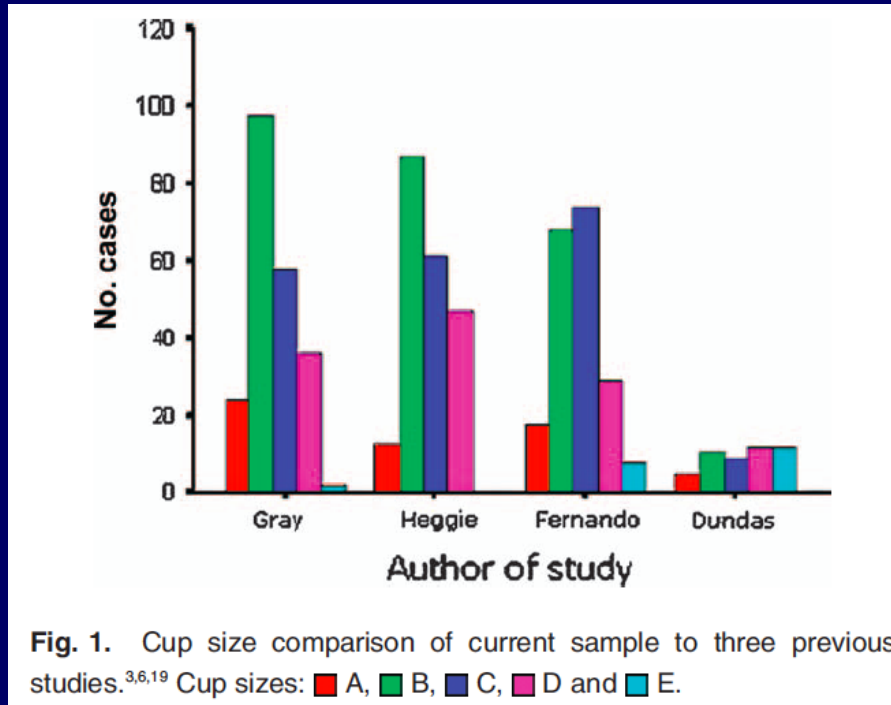
KL Dundas,^{1,2,†} J Atyeo² and J Cox²

¹Nepean Cancer Care Centre, Sydney West Cancer Network, Nepean Hospital and ²Faculty of Health Sciences, The University of Sydney, Sydney, New South Wales, Australia

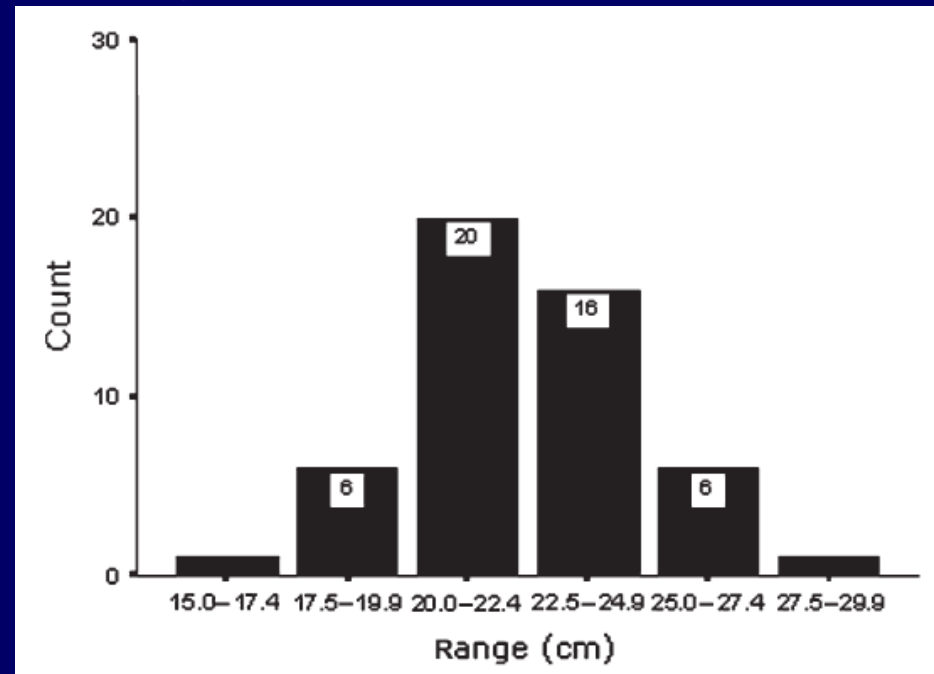
Tentativa de padronização do volume mamário para radioterapia

Radioterapia hipofracionada mamas volumosas

Definição pelo tamanho do *soutien*



Definição pela linha entrada-saída



Definição pelo volume de PTV ($\geq 1000\text{cc}$)

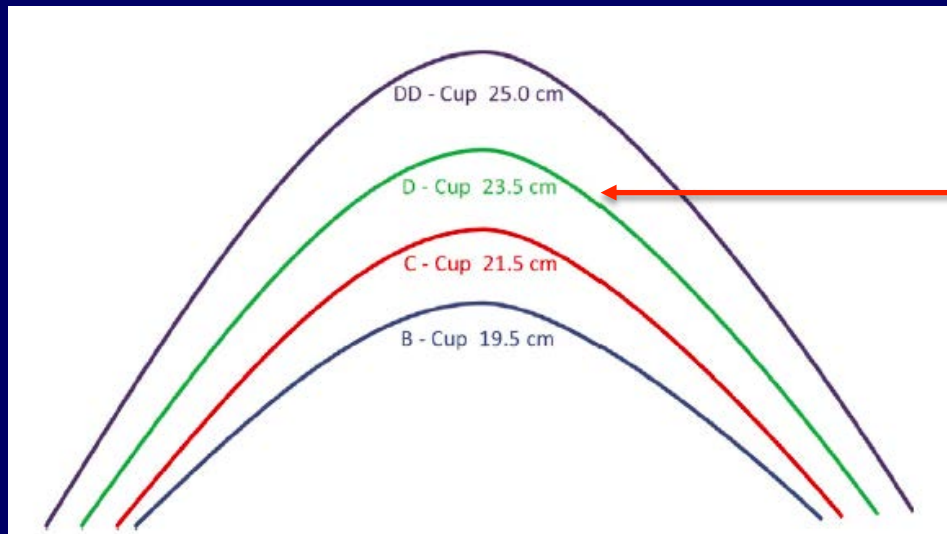
Radioterapia hipofracionada mamas volumosas

Classificação por:

- Peso >80Kg
- Soutien* ≥ 40 polegadas (101,6cm)
- Volume do *soutien* $\geq D$
- Separação tangencial ≥ 23 cm
- Volume do PTV >1000cc (consenso atual com limite de 600cc)

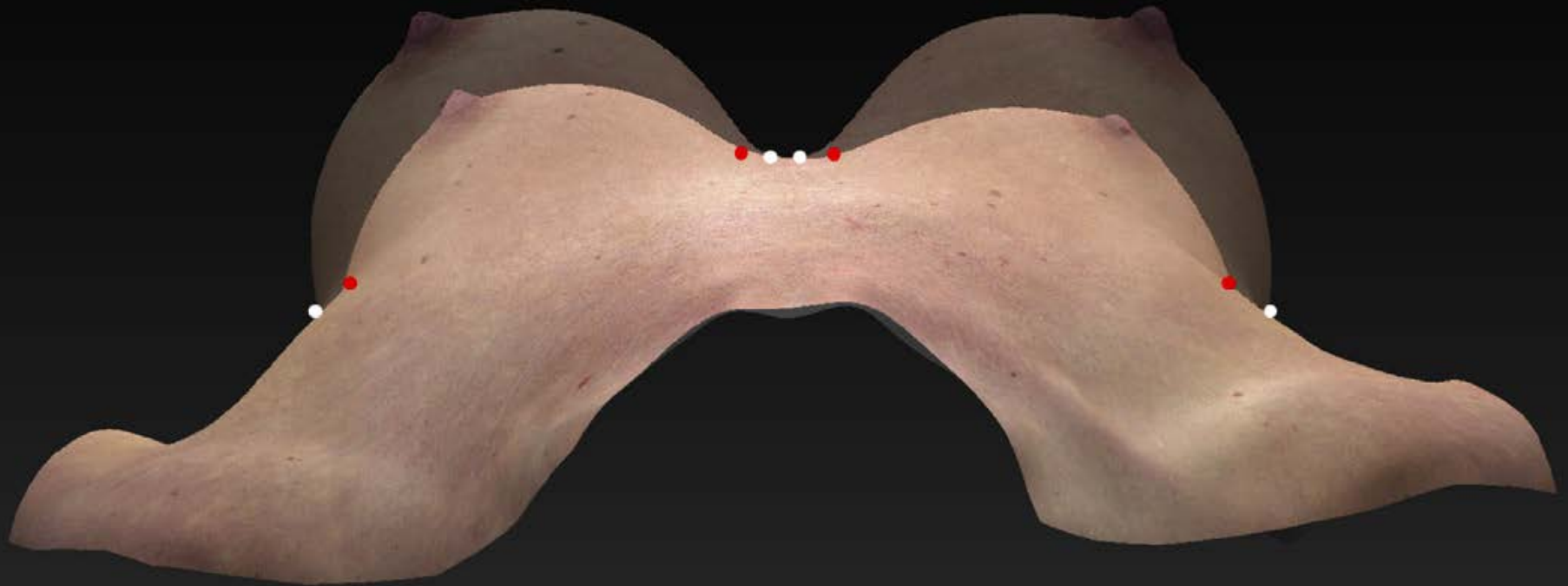
The Standardization of Bra Cup Measurements Redefining Bra Sizing Language

Bradley P. Bengtson, MD^{a,b,*}, Caroline A. Glicksman, MD^{c,d}



Mama volumosa

Radioterapia hipofraccionada mamas volumosas



What Is the Standard Volume to Increase a Cup Size for Breast Augmentation Surgery? A Novel Three-Dimensional Computed Tomographic Approach

Reconstrução 3D para volumetria da mama

Radioterapia hipofraccionada mamas volumosas

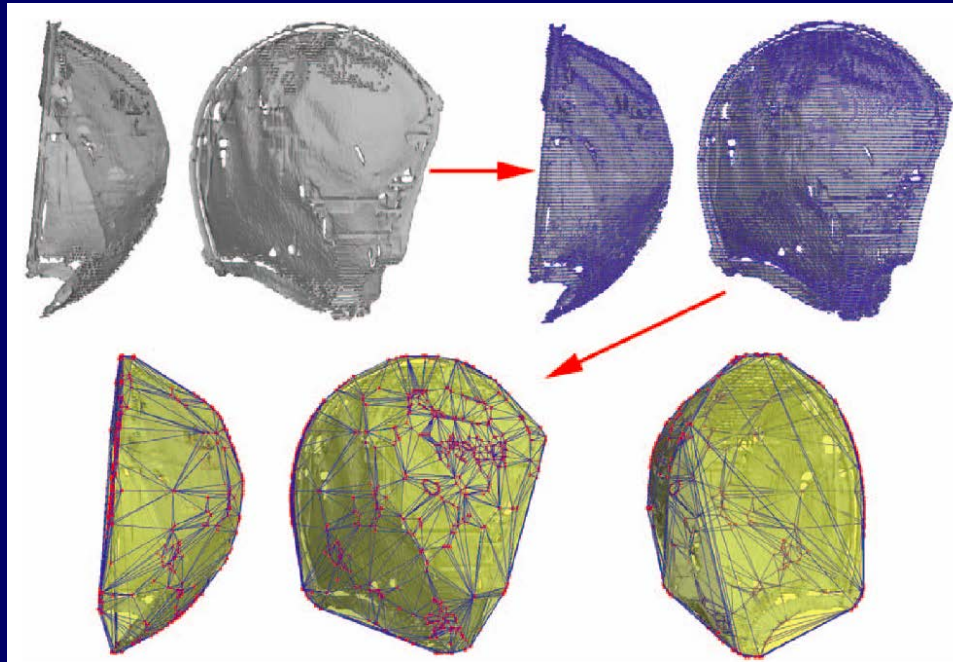


Table 2. Volume Capacity of Each Bra Cup Size Using the Three-Dimensional Computed Tomographic Reconstruction Method

Brand	B	C	D	DD	E
1	433	632	728	908	1040
2	491	576	704	797	924
3	467	696	834	920	1053

Radioterapia hipofracionada mamas volumosas



Hipofracionamento 42,56Gy+boost 10Gy@2,5Gy
Isodose de prescrição 93%; normalizado a 100%
Volume de 832cc

Radioterapia hipofracionada mamas volumosas

Alta



Retorno após 01 mês



Radioterapia hipofraccionada X convencional

Changes in radiotherapy fractionation – breast cancer

Author:

John Yarnold

Professor of Clinical Oncology

Division of Radiotherapy and Imaging

The Institute of Cancer Research

London

Email: john.yarnold@icr.ac.uk

BJR UNCORRECTED PROOFS

Radioterapia hipofracionada X convencional

Table 1. Patient and treatment characteristics in 4 randomised trials testing hypofractionated radiotherapy after surgery for early breast cancer

	START-P (8)	START-A (10)	START-B (11)	Ontario (7)
Years accrual	1986-1998	1998-2002	1999-2001	1993-1996
Total number of patients	1410	2236	2215	1234
Standard arm (Gy/fr/weeks)	50/25/5	50/25/5	50/25/5	50/25/5
Test arm A (Gy/fr/weeks)	42.9/13/5	41.6/13/5	40.0/15/5	42.5/16/3.1
Test arm B (Gy/fr/weeks)	39/13/5	39/13/5	n/a	n/a
Mean age (years)	54.5	57.2	57.4	Not reported
Node+ (%)	32.7	28.8	22.8	0
Mastectomy (%)	0	15	8	0
Tumour size \geq T2 (%)	42.5 ^a	48.6 ^b	35.9 ^b	20.0 ^b
Boost (%)	74.5	60.6	42.6	0
Chemotherapy (%)	13.9	35.5	22.2	11
Regional radiotherapy (%)	20.6	14.2	7.3	0

^a Clinical T stage

^b Pathological stage

Radioterapia hipofracionada X convencional

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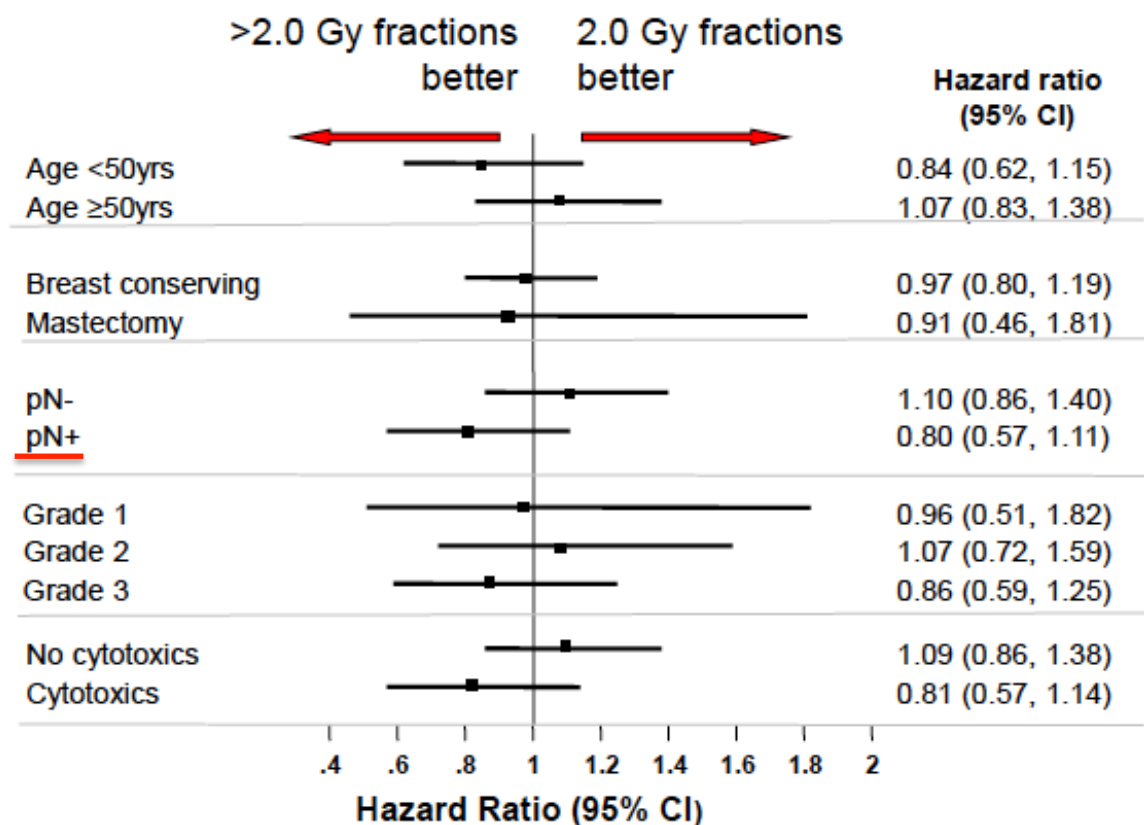
^b Pathological stage

Radioterapia hipofraccionada X convencional

Table 5a. START pilot, A & B (n=5861): patient and treatment characteristics (13).

	Number patients
Age <50yrs	1389
Age ≥50yrs	4472
Breast conserving	5348
Mastectomy	513
pN-	4318
<u>pN+</u>	<u>1421</u>
Grade 1	1213
Grade 2	2398
Grade 3	1271
No cytotoxics	4346
Cytotoxics	1480

Table 5b. Metanalysis of tumour control: START pilot, A and B (n=5861) (13).



Radioterapia hipofracionada X convencional

Comparando BED e toxicidade cardíaca com hipofracionamento

Table 6. Current whole breast hypofractionation is likely less damaging to the heart (17).

α/β value	Equivalent Total /Dose in 2 Gy fractions	
	50 Gy/25F	40Gy/15F
3.0 Gy	50.0	45.5
1.5 Gy	50.0	48.0

Radioterapia hipofracionada X convencional

Comparando BED e toxicidade cardíaca com hipofracionamento

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Radiation therapy for the whole breast: Executive summary of an American Society for Radiation Oncology (ASTRO) evidence-based guideline



Table 1 Patients for whom consensus supports use of HF-WBI: A comparison of the 2011 and 2018 ASTRO Guidelines *

Factor	2011 Guideline	2018 Guideline
Age	≥50 years	Any
Stage	T1-2 N0	Any stage provided intent is to treat the whole breast without an additional field to cover the regional lymph nodes
Chemotherapy	None	Any chemotherapy
Dose homogeneity	±7% in the central axis	Volume of breast tissue receiving >105% of the prescription dose should be minimized regardless of dose-fractionation

Results: For women with invasive breast cancer receiving WBI with or without inclusion of the low axilla, the preferred dose-fractionation scheme is hypofractionated WBI to a dose of 4000 cGy in 15 fractions or 4250 cGy in 16 fractions. The guideline discusses factors that might or should affect fractionation decisions. Use of boost should be based on shared decision-making that



National
Comprehensive
Cancer
Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Breast Cancer

Version 1.2018 — March 20, 2018

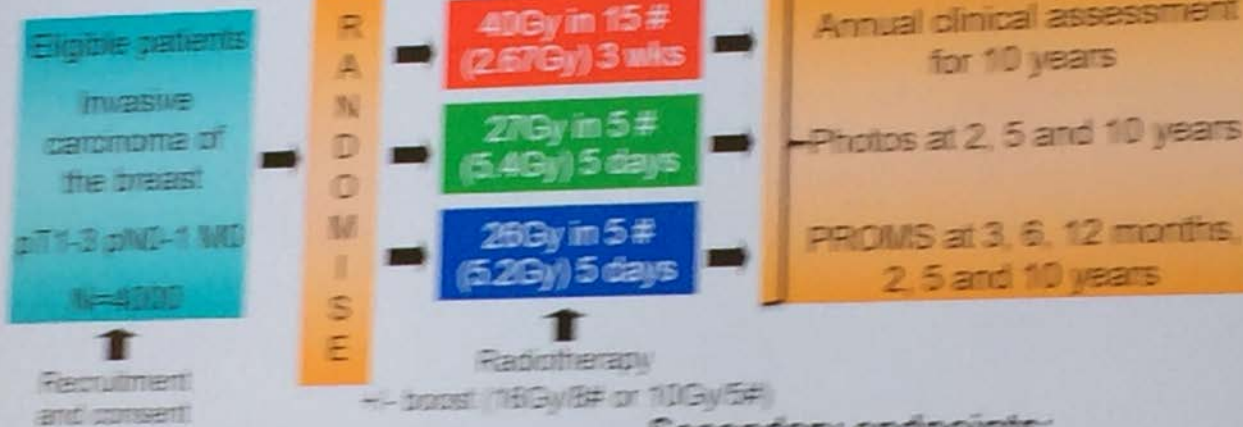
NCCN.org

NCCN Guidelines for Patients® available at www.nccn.org/patients

Whole Breast Radiation

Target definition is the breast tissue in entirety. The whole breast should receive a dose of 45–50.4 Gy in 25–28 fractions or 40–42.5 Gy in 15–16 fractions (hypofractionation is preferred). All dose schedules are given 5 days per week. A boost to the tumor bed is recommended in patients at higher risk for recurrence. Typical boost doses are 10–16 Gy in 4–8 fractions.

Trial design



Primary endpoint:

- ipsilateral local tumour control

Median follow-up: 4 years

Secondary endpoints:

- early & late AE in normal tissues
- quality of life
- contralateral primary tumours
- regional & distant metastases
- survival

App Store Preview



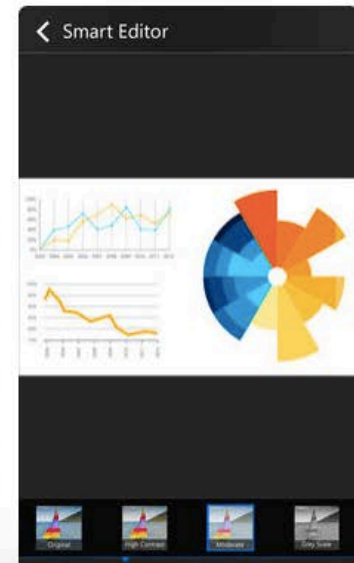
U Scanner - Photo to PDF 4+

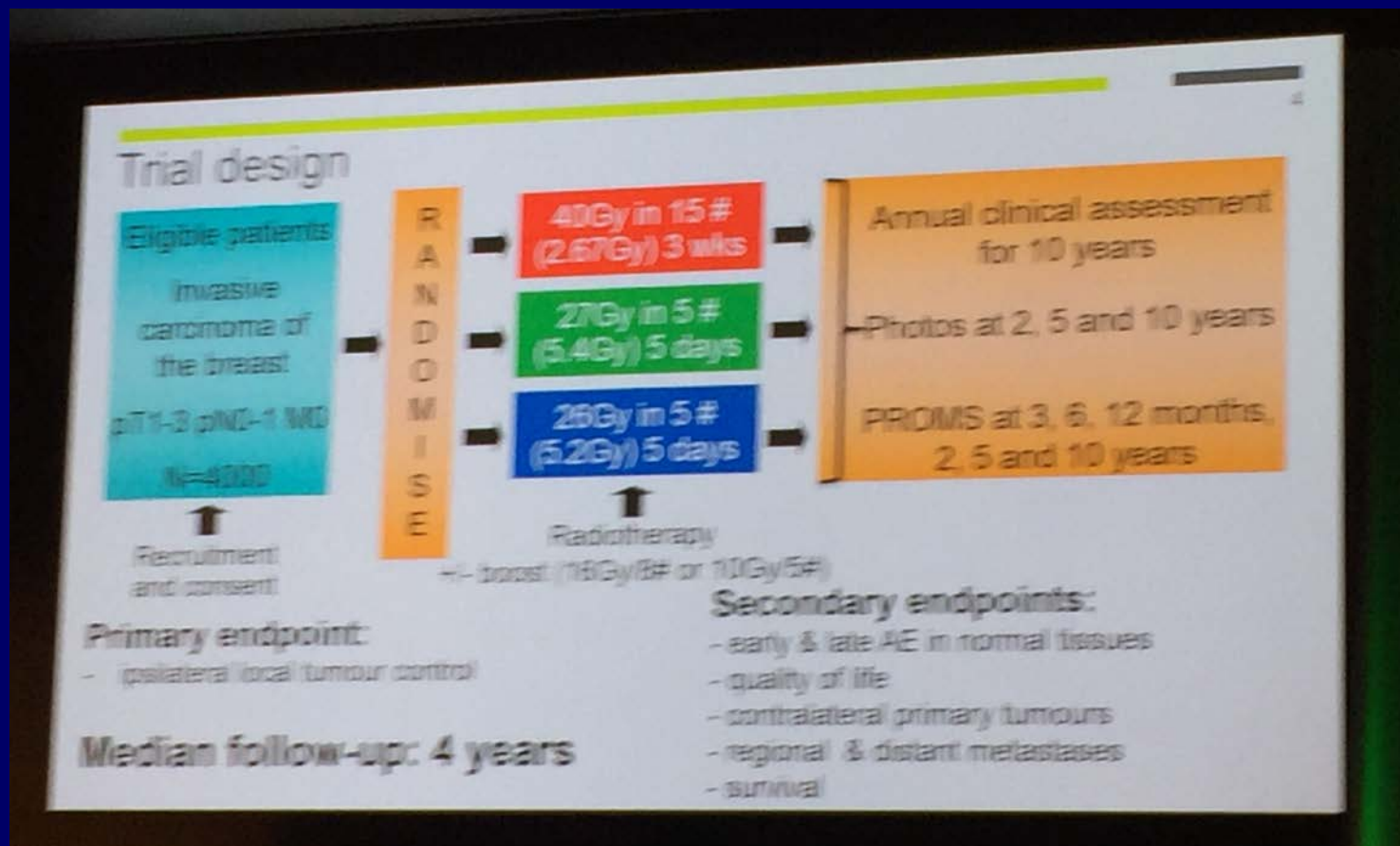
CyberLink

★★★★☆ 4.5, 27 Ratings

Free · Offers In-App Purchases

iPhone Screenshots





Prospectivo aleatorizado com 4000 pctes.; mediana de 4 anos
 CDI pT1-3pN0-1 *End point* 1º - SLD 2º - SLM, SG, toxicidade

40Gy (15X2,67Gy)

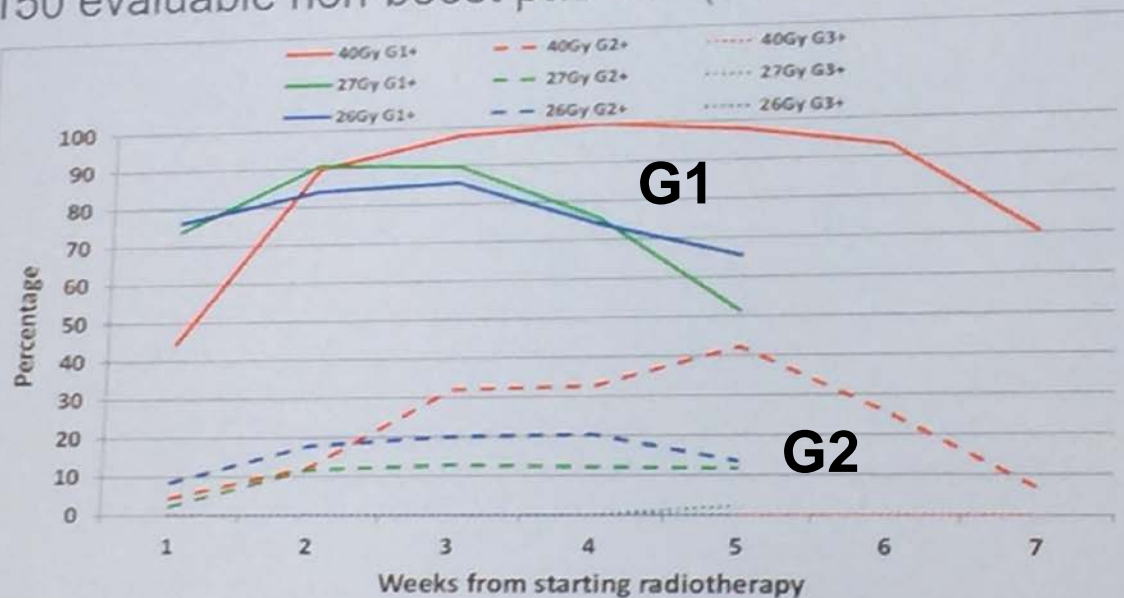
27Gy (5X5,4Gy)

26Gy (5X5,2Gy)

Toxicidade (G1, G2 e G3) ao longo das semanas de tto

Acute toxicity study

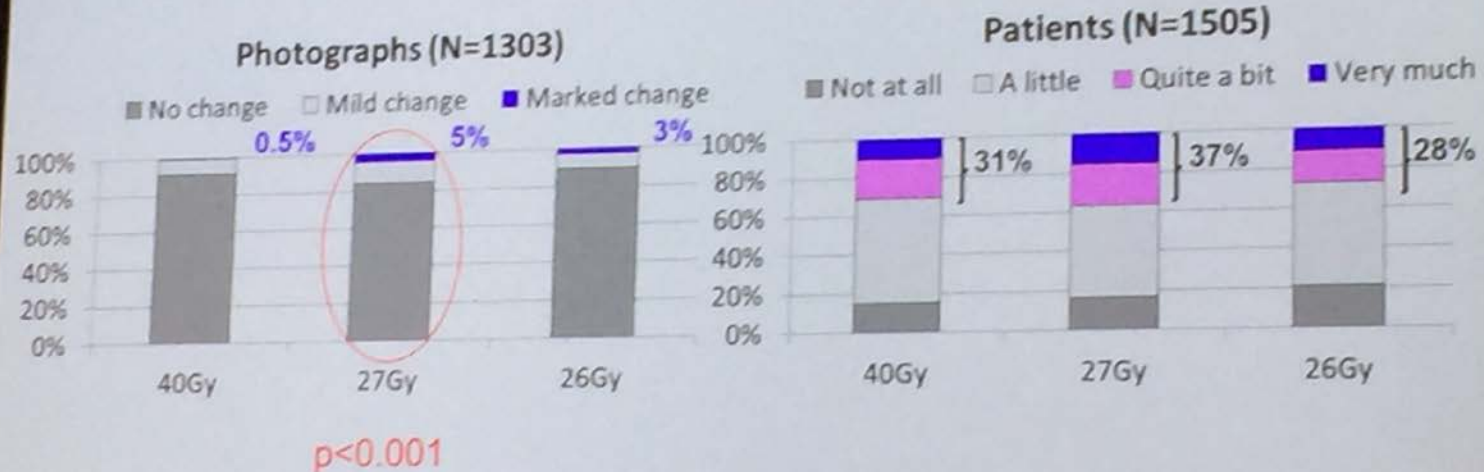
Clinical assessments of skin toxicity graded by CTCAE criteria in 150 evaluable non-boost patients (7 centres)



Brunt et al.
Radiother
Oncol 2016

Alteração fotográfica importante / Impressão da paciente

Photographic & patient assessments of overall change in breast appearance at 2 years



Conclusions

- Levels of marked late AE were low in all groups
- 27Gy/5# is consistent with 50Gy/25# in 5 weeks
- 26Gy/5# similar to 40Gy/15# over 3 weeks
- Mature follow-up will allow interpolation to confirm equivalent 5# schedule
- Ongoing lymphatic sub-study comparing 40Gy/15# vs 26Gy/5#

Radioterapia hipofracionada X convencional

Hypofractionated Postmastectomy Radiation Therapy Is Safe and Effective: First Results From a Prospective Phase II Trial

Atif J. Khan, Matthew M. Poppe, Sharad Goyal, Kristine E. Kokeny, Thomas Kearney, Laurie Kirstein, Deborah Toppmeyer, Dirk F. Moore, Chunxia Chen, David K. Gaffney, and Bruce G. Haffty

Fase II com 69 ptes.

Ca. mama estágio II e IIIa e mastectomia com ou sem reconstrução

Dose: 36,63Gy em 11 frações de 3,33Gy \pm boost de 13,2Gy (4X3,33Gy)

Seguimento mediano 32 meses

Perda do implante em 24% e correção cirúrgica não planejada 8%

Trials registrados no www.clinicaltrials.org

NIH U.S. National Library of Medicine

ClinicalTrials.gov

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[Home](#) > [Search Results](#) > Study Record Detail

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Trial record **1 of 1** for: NCT02384733

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Hypofractionated Loco-regional Adjuvant Radiation Therapy of Breast Cancer Combined With a Simultaneous Integrated Boost



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02384733

[Recruitment Status](#) ⓘ : Recruiting

[First Posted](#) ⓘ : March 10, 2015

[Last Update Posted](#) ⓘ : August 1, 2017

See [Contacts and Locations](#)

Sponsor:

Danish Breast Cancer Cooperative Group

Collaborator:

Danish Cancer Society

Information provided by (Responsible Party):

Birgitte Offersen, Danish Breast Cancer Cooperative Group

Prospectivo de intervenção dinamarquês - BCS ou mastectomia e indicação de RT adjuvante loco-regional
RT 50Gy@2Gy *versus* **40Gy@2,67 e boost concomitante**
End point - toxicidade; secundário controle local

Trials registrados no www.clinicaltrials.org

NIH U.S. National Library of Medicine

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Trial record **2 of 6** for: hypo fractionated post-mastectomy | breast cancer

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Hypofractionated Radiation Therapy After Mastectomy in Preventing Recurrence in Patients With Stage IIa-IIIa Breast Cancer



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03414970

[Recruitment Status](#) ⓘ : Recruiting

[First Posted](#) ⓘ : January 30, 2018

[Last Update Posted](#) ⓘ : February 23, 2018

See [Contacts and Locations](#)

Sponsor:

Alliance for Clinical Trials in Oncology

Collaborator:

National Cancer Institute (NCI)

Information provided by (Responsible Party):

Alliance for Clinical Trials in Oncology

Prospectivo fase III - mama N1-2 e **mastectomia com reconstr.**
Permite QT neo ou adjuvante pós-mastectomia; **permite RT drenagem**
RT 5-6 semanas *versus* hipo em 3-4 semanas; sem boost
End point - toxicidade, controle local, qualidade de vida

Trials registrados no www.clinicaltrials.org

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Trial record **6 of 6** for: hypo fractionated post-mastectomy | breast cancer

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Radiotherapy After Mastectomy for Breast Cancer Patients at Increased Risk of Local Recurrence



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03101683

[Recruitment Status](#) ⓘ : Not yet recruiting

[First Posted](#) ⓘ : April 5, 2017

[Last Update Posted](#) ⓘ : September 5, 2017

See [Contacts and Locations](#)

Sponsor:

Fondazione del Piemonte per l'Oncologia

Information provided by (Responsible Party):

Fondazione del Piemonte per l'Oncologia

Prospectivo de intervenção italiano - mama pTis, T1-2 ou N1 e **mastectomia com reconstrução imediata e alto risco** (triplo neg., margens exíguas ou +, invasão vascular, Her2 positivo, idade ≤ 50 a) RT 50Gy@2Gy (histórico) *versus* 40Gy@2,5 (15 frações)
End point - toxicidade, controle local, qualidade de vida; secundário SG

Trials registrados no www.clinicaltrials.org

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Trial record **6 of 9** for: hypofractionation mastectomy | breast cancer

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Study of Radiation Fractionation on Patient Outcomes After Breast REConstruction (FABREC) for Invasive Breast Carcinoma



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT03422003

[Recruitment Status](#) ⓘ : Not yet recruiting

[First Posted](#) ⓘ : February 5, 2018

[Last Update Posted](#) ⓘ : February 5, 2018

See [Contacts and Locations](#)

Sponsor:

Dana-Farber Cancer Institute

Information provided by (Responsible Party):

Rinaa Punglia, MD MPH, Dana-Farber Cancer Institute

Prospectivo de intervenção Dana Farber - pT1-3 com indicação RT pelo NCCN; reconstrução imediata com **prótese/expansor** RT 50Gy@2Gy plastrão 46-50Gy drenagem *versus* 42,56Gy@2,66Gy plastrão e 39,9Gy@2,66Gy em **drenagem (mamária, FSC e/ou axila)** End point - toxicidade em 6 meses (score FACT-B)

Considerações para RT hipofracionada

- Modelo biológico de 15 / 16 frações possui nível I de evidência em SLD, SG; menos representado em subgrupos específicos (também sub-representados no fracionamento convencional!)
- Modelo biológico sugere maior proteção cardíaca com hipofracionamento; na prática sugere-se proteger o coração a despeito do fracionamento empregado
- Retirar a mama muda a tolerância do tecido remanescente? Definitivamente não. Meta-análise dos START *trials* - 513 pctes. - apesar de baixo poder estatístico tem HR e intervalos de confiança com idêntica toxicidade entre mastectomia e BCS.

Considerações para RT hipofracionada

- Mito de toxicidade pelo hipofracionamento em mamas volumosas; modelo teórico de *alfa-beta* coloca o hipofracionamento como mais seguro que o convencional; confirmado pelos *trials* já publicados
- “Se há indicação de radioterapia ela pode ser por hipofracionamento moderado”
- Critério de exclusão do START foi reconstrução imediata; embora o grupo START *Trialist* tenha a “opinião de ser melhor opção que fracionamento *standard*, pela ausência de dados há sugestão de uso de fracionamento convencional”.

Obrigado!



hanriot@yahoo.com