



**L'irradiazione della mammella con campi tangenti standard non mostra un'adeguata copertura e distribuzione di dose al I-II livello dei linfonodi ascellari e all'area del linfonodo sentinella.**

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I risultati dei trials ACOSOG Z0011 e NSABP B32 non hanno dimostrato alcun vantaggio della dissezione ascellare (ALND) nelle pazienti con micrometastasi del linfonodo sentinella, quando i pazienti sono sottoposti a terapia sistemica e irradiazione mammaria. In questo studio retrospettivo è stata valutata la distribuzione di dose e la copertura del I-II livello ascellare e l'area del linfonodo sentinella (SLN).

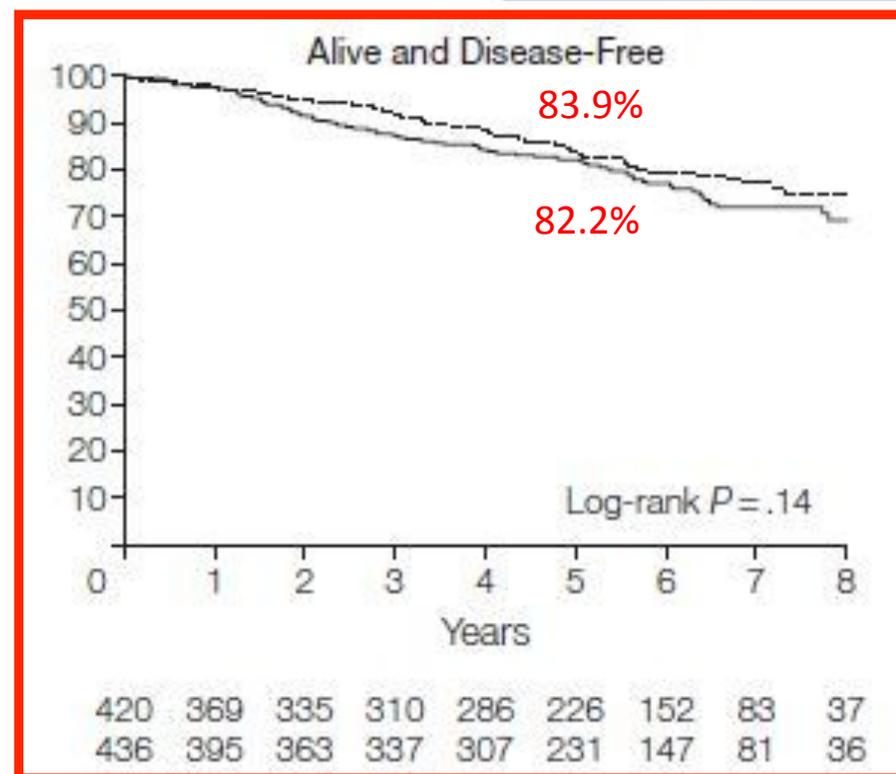
# Axillary Dissection vs No Axillary Dissection in Women With Invasive Breast Cancer and Sentinel Node Metastasis

## A Randomized Clinical Trial

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Characteristic	No. (%)	
	ALND (n = 420)	SLND Alone (n = 436)
Age, median (range), y	56 (24-92)	54 (25-90)
Missing	7	10
Clinical T stage		
T1	284 (67.9)	303 (70.6)
T2	134 (32.1)	126 (29.4)
Missing	2	7
Tumor size, median (range), cm	1.7 (0.4-7.0)	1.6 (0.0-5.0)
Missing	6	14
Receptor status		
ER+/PR+	256 (66.8)	270 (68.9)
ER+/PR-	61 (15.9)	54 (13.8)
ER-/PR+	3 (0.8)	4 (1.0)
ER-/PR-	63 (16.5)	64 (16.3)
Missing	37	44
Yes	129 (40.6)	113 (35.2)
No	189 (59.4)	208 (64.8)
Missing	102	115

Modified Bloom-Richardson score		
1	71 (22.0)	81 (25.6)
2	158 (48.9)	148 (46.8)
3	94 (29.1)	87 (27.5)
Missing	97	120
Tumor type		
Infiltrating ductal	344 (82.7)	356 (84.0)
Infiltrating lobular	27 (6.5)	36 (8.5)
Other	45 (10.8)	32 (7.5)
Missing	4	12
Lymph node metastases		
0	4 (1.2)	29 (7.0)
1	199 (58.0)	295 (71.1)
2	68 (19.8)	76 (18.3)
3	25 (7.3)	11 (2.7)
≥4	47 (13.7)	4 (1.0)
Missing	77	21

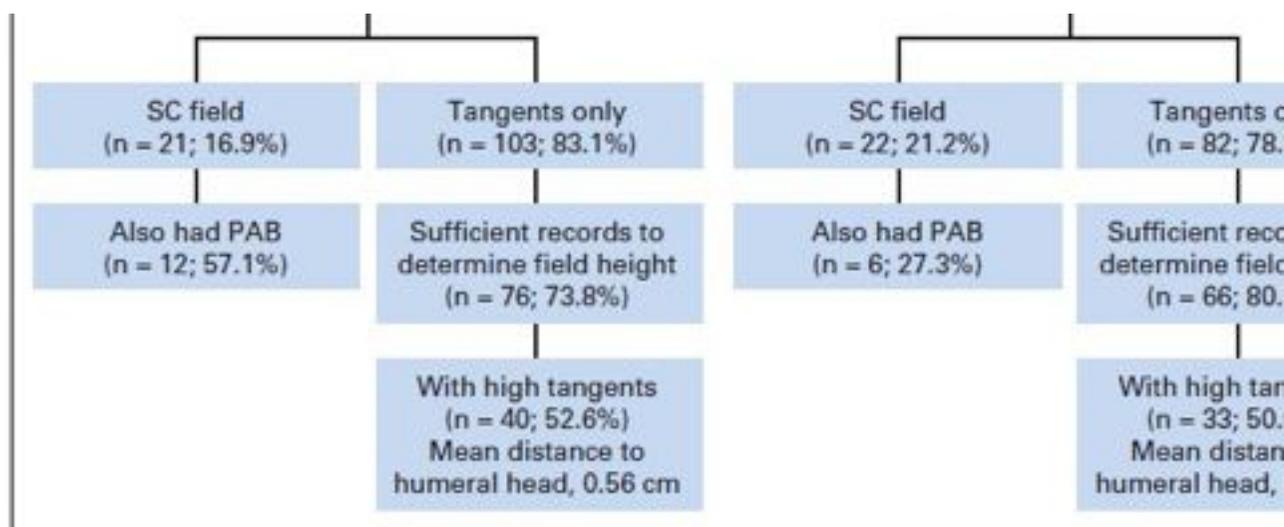


## Radiation Field Design in the ACOSOG Z0011 (Alliance) Trial

*Reshma Jagsi, Manjeet Chadha, Janaki Moni, Karla Ballman, Fran Laurie, Thomas A. Buchholz, Armando Giuliano, and Bruce G. Haffty*

### Conclusion

Most patients treated in Z0011 received tangential RT alone, and some received no RT at all. Some patients received directed nodal irradiation via a third field. Further research is necessary to determine the optimal RT approach in patients with low-volume axillary disease treated with mastectomy and axillary dissection (MAD) alone.

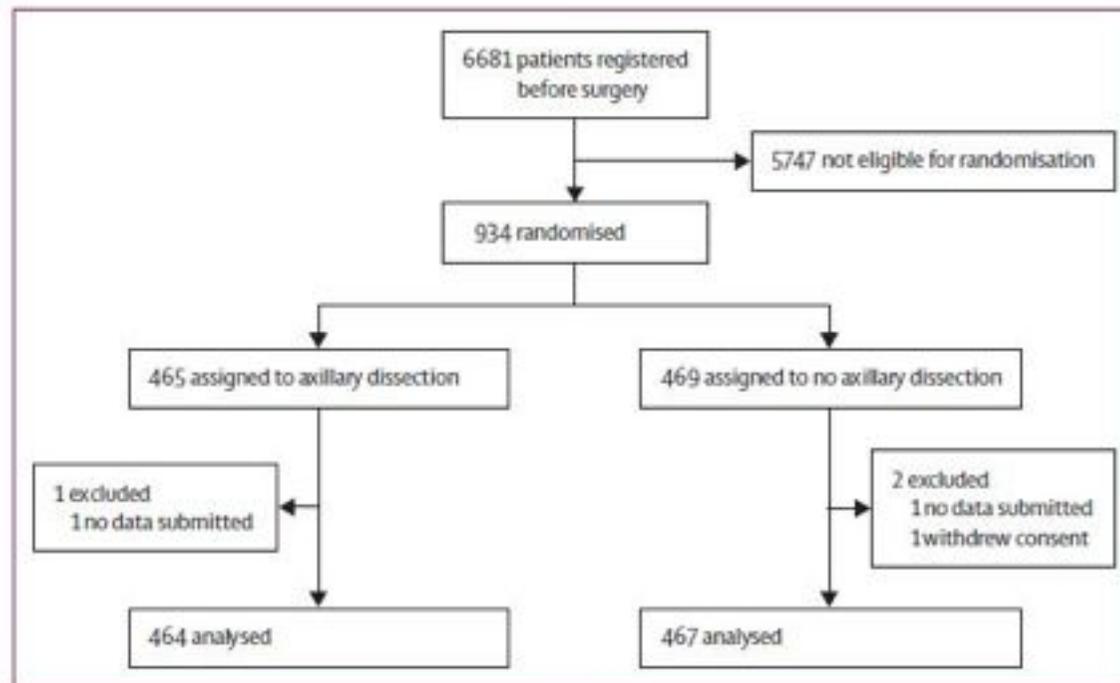


# Axillary dissection versus no axillary dissection in patients with sentinel-node micrometastases (IBCSG 23-01): a phase 3 randomised controlled trial



Viviana Galimberti, Bernard F Cole, Stefano Zurrada, Giuseppe Viale, Alberto Luini, Paolo Veronesi, Paola Baratella, Camelia Chifu, Manuela Sargenti, Mattia Intra, Oreste Gentilini, Mauro G Mastropasqua, Giovanni Mazzaro, Samuele Massarut, Jean-Rémi Garbay, Janez Zgajnar, Hanne Galatius, Angelo Recalcati, David Littlejohn, Monika Bamert, Marco Colleoni, Karen N Price, Meredith M Regan, Aron Goldhirsch, Alan S Coates, Richard D Gelber, Umberto Veronesi, for the International Breast Cancer Study Group Trial 23-01 investigators

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	Axillary dissection (n=464)	No axillary dissection (n=467)
<b>Disease-free survival events*</b>		
Total	69 (15%)	55 (12%)
Breast cancer events		
Local	10 (2%)	8 (2%)
Regional	1 (<1%)	5 (1%)
Distant	34 (7%)	25 (5%)
Contralateral breast	3 (<1%)	9 (2%)
Non-breast cancer events		
Second (non-breast) primary†	20 (4%)	6 (1%)
Death without cancer event	1 (<1%)	2 (<1%)
<b>Deaths</b>		
Total	19 (4%)	17 (4%)

\*Includes all breast cancer events, all non-breast cancer events, and deaths with cause unknown. †Types (number) of second primaries in the group with axillary dissection were gastrointestinal (four), genitourinary (two), gynaecological (six), haematological (two), laryngeal (two), lung (one), and sarcoma (three). Types (number) in the group without axillary dissection were gastrointestinal (two), gynaecological (three), and melanoma (one).

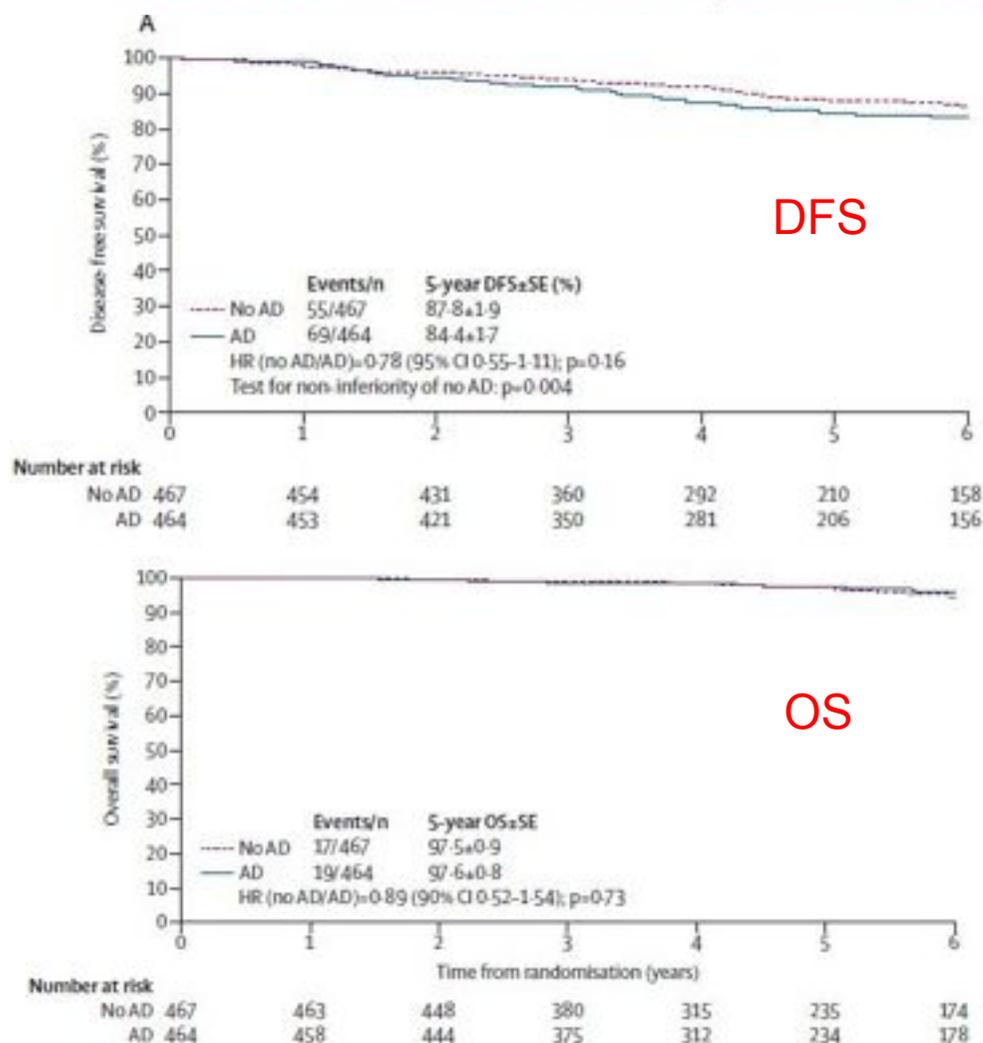
**Table 3: Disease-free survival events and deaths at 5.0 years median follow-up of intention-to-treat population**

# Axillary dissection versus no axillary dissection in patients with sentinel-node micrometastases (IBCSG 23-01): a phase 3 randomised controlled trial



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	Axillary dissection (n=447)	No axillary dissection (n=453)	p value†
Sensory neuropathy	82 (18%)	55 (12%)	0.012
Grade 1	60 (13%)	40 (9%)	
Grade 2	15 (3%)	6 (1%)	
Grade 3	1 (<1%)	0	
Grade 4	0	0	
Unknown grade	6 (1%)	9 (2%)	
Lymphoedema	59 (13%)	15 (3%)	<0.0001
Grade 1	33 (7%)	10 (2%)	
Grade 2	20 (4%)	3 (<1%)	
Grade 3	2 (<1%)	0	
Grade 4	1 (<1%)	0	
Unknown grade	3 (<1%)	2 (<1%)	
Motor neuropathy	37 (8%)	13 (3%)	0.0004
Grade 1	25 (6%)	11 (2%)	
Grade 2	9 (2%)	1 (<1%)	
Grade 3	3 (<1%)	1 (<1%)	
Grade 4	0	0	
Unknown grade	0	0	

\*Excludes 31 patients (17 in the axillary dissection group and 14 in the no-axillary-dissection group) who did not receive the randomly assigned treatment. †Based on Fisher's exact test comparison of the occurrence of any grade event across treatment groups.

**Table 2: Long-term surgical events\***

# Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update

*Gary H. Lyman, Sarah Temin, Stephen B. Edge, Lisa A. Newman, Roderick R. Turner, Donald L. Weaver, Al B. Benson III, Linda D. Bosserman, Harold J. Burstein, Hiram Cody III, James Hayman, Cheryl L. Perkins, Donald A. Podoloff, and Armando E. Giuliano*

## CLINICAL QUESTION 2.1

Is it necessary for all patients with metastatic findings on SNB to undergo BCS with whole-breast radiotherapy?

## RECOMMENDATION 2.1

Clinicians should not recommend ALND for women with early-stage breast cancer and one or two SLN metastases who will undergo BCS with conventionally fractionated whole-breast radiotherapy. Type: evidence based; benefits outweigh harms. Evidence quality: strong. Strength of recommendation: high.

Clinicians may also consider this recommendation with caution in cases of women with large or bulky metastatic axillary SLNs and those with gross extranodal extension of the tumor. These were exclusion criteria for Z0011. The former were represented by few patients.



## axillary nodes radiotherapy an alternative to surgery?

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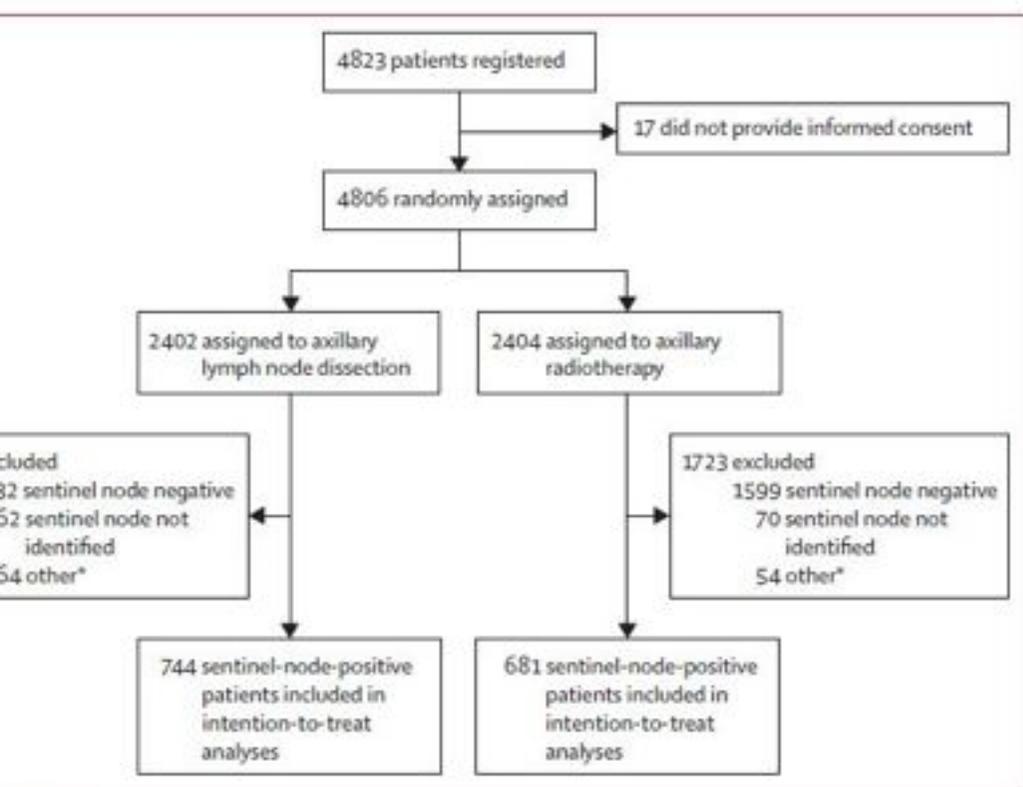
Study	Type	N	Year	Patients	HR status	FU median	pT1	Age	Results
Kamakura study [25]	-R	1517 pts T1–T2cN0, All BCS, all WBI A) 80 pts ALND B) 1134 pts tangential 2 field RT (no ALND) C) 303 pts 3-field RT (no ALND)	1983–2002	80% had chemotherapy. Postmenopausal pts with ER+ tumour also had tamoxifen.	A) 44/31% ER+/PgR+ B) 62/62% ER+/PgR+ C) 51/40% ER+/PgR+	A) 13.4 yr B) 4.6 yr C) 10.2 yr	38–47%	Median 43–48 yr	Group A) 1 pt (1.3%) had axillary recurrence (ax rec) Group B) 35 (3%) had ax rec, 10 yr cumulative ax rec rate: 1.3% vs 4.6% (ALND vs RT) 5 yr ax rec rates 2.5% vs 1.7% (2 field vs 3 field), $P = 0.18$ 5 yr regional rec rates 4.8% vs (2 vs 3 fields) $P = 0.048$ (reg rec = supraclav rec+ax rec) No difference in OS among groups Regional recurrence at 5 yr: 1.5% vs 1.5% in RT vs no-RT group. OS similar, but DFS better in ALND
Deventer study [28]	-R	180 pts T1/T2 cN0 no ALND but reg RT + tamoxifen 341 pts T1/T2 cN0 ALND (if pN+ the pt also had nodal RT)	1991–2000	In ALND pts: pN0:76.8% pN1:20.5% pN2:0.3%	HR unknown No ALND: 99% endocrine and 0.6% chemotherapy ALND: 22% endocrine and 10% chemotherapy 77% ER+	7.2 yr	68% (no ALND) 80% (ALND)	≥50 yr	21% in ALND group were pN+ (57% 1LN+, 34% 2–3 LN+, 9% 4+ LN+) At 15 yr isolated reg rec was similar in ALND vs RT group, $P = 0.04$ Distant metastasis and overall survival was no different
Institut Curie trial [26]	+R	658 pts, T <3 cm, cN0, <70 yr All BCS and WBI A) 326 pts, ALND B) 332 pts, No ALND but Ax RT given	1982–1987		A) 19% received CMF, 14% endocrine therapy B) 9% received CMF, 8% endocrine therapy	15 yr	67%	Mean age group A/B: 52/50.6 yr	Type of met/further nodal dis: Macromet 63%/41% Micromet 25%/18% Single cell 12%/18%
The EORTC 10981 AMAROS trial [27]	+R	647 pts SN+, cN0, 697 pts planned accrual R: pts SN with T 0.5–3 cm 1) ALND + WBI 2) WBI + reg RT Reg RT: 50 Gy/25 fr levels I + II + III and medial part of fossa supraclav	2001–2010	Premeno: 28% Postmeno: 61% Grades I, II, III 28, 43, 25%	Not reported		74%	Median 57 yr (24–87 yr)	

# Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS): randomised, multicentre, open-label, phase 3 non-inferiority trial



Donker, Geertjan van Tienhoven, Marieke E Straver, Philip Meijnen, Cornelis J H van de Velde, Robert E Mansel, Luigi Cataliotti, Len Westenberg, Jean H G Klinkenbijl, Lorenzo Orzalesi, Willem H Bouma, Huub C J van der Mijle, Gerd A P Nieuwenhuijzen, Anne C Veltkamp, Leen Slaets, Nicole J Duez, Peter W de Graaf, Thijs van Dalen, Andreas Marinelli, Herman Rijna, Marko Snoj, Nigel J Bundred, Y S Merkus, Yazid Bekkacemi, Patrick Petignat, Dominic A X Schinagl, Corneel Coens, Carlo G M Messina, Jan Bogaerts, Emiel J T Rutgers

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**Final profile**  
 patients who did not undergo sentinel node biopsy or the sentinel node results were unknown (12 in the lymph node dissection group and 12 in the axillary radiotherapy group), had only a positive non-sentinel node (6 and 13), had a positive sentinel node that was not located in the axilla (nine and 13), or only isolated nodes in the sentinel node after the protocol amendment (27 and 23).

	Axillary lymph node dissection (n=744)	Axillary radiotherapy (n=681)
<b>Baseline characteristics</b>		
Age, years	56 (48-64)	55 (48-63)
Menopausal status		
Premenopausal	283 (38%)	289 (42%)
Postmenopausal	449 (60%)	384 (56%)
Missing	12 (2%)	8 (1%)
Preoperative ultrasound axilla		
Done	440 (59%)	419 (62%)
Not done	304 (41%)	262 (38%)
Tumour on dominant side		
Yes	377 (51%)	329 (48%)
No	352 (47%)	336 (49%)
Bilateral	8 (1%)	2 (<1%)
Missing	7 (1%)	14 (2%)
Clinical tumour size		
Median (mm, IQR)	17 (13-22)	18 (13-23)
0-2 cm	612 (82%)	533 (78%)
2-5 cm	132 (18%)	143 (21%)
>5 cm	0 (0%)	1 (<1%)
Missing	0 (0%)	4 (1%)
Tumour type		
Infiltrating ductal	563 (76%)	515 (76%)
Infiltrating lobular	100 (13%)	99 (15%)
Other	81 (11%)	66 (10%)
Missing	0 (0%)	1 (<1%)
Grade		
I	179 (24%)	154 (23%)
II	356 (48%)	311 (46%)
III	192 (26%)	200 (29%)
Missing	17 (2%)	16 (2%)
Type of breast surgery		
Breast-conserving surgery	609 (82%)	557 (82%)
Mastectomy	127 (17%)	121 (18%)
Missing	8 (1%)	3 (<1%)

(Table 1 continues on next page)

	Axillary lymph node dissection (n=744)	Axillary radiotherapy (n=681)
<b>Sentinel node characteristics</b>		
(Continued from previous page)		
<b>Adjuvant radiotherapy</b>		
Breast	597 (80%)	546 (80%)
Chest wall	34 (5%)	51 (7%)
Internal mammary chain	72 (10%)	65 (10%)
<b>Systemic treatment administered</b>		
Any systemic treatment	666 (90%)	632 (90%)
Chemotherapy	453 (61%)	418 (61%)
Hormonal therapy	585 (79%)	525 (77%)
Immunotherapy	45 (6%)	44 (6%)
<b>Number of sentinel nodes removed</b>		
1	332 (45%)	293 (43%)
2	201 (27%)	217 (32%)
3	127 (17%)	105 (15%)
≥4	84 (11%)	66 (10%)
<b>Number of positive sentinel nodes</b>		
1	581 (78%)	532 (75%)
2	127 (17%)	134 (20%)
3	29 (4%)	27 (4%)
≥4	7 (1%)	8 (1%)
<b>Size of the largest sentinel node metastasis</b>		
Macrometastasis	442 (59%)	419 (62%)
Micrometastasis	235 (32%)	195 (29%)
Isolated tumour cells	87 (12%)	67 (10%)
<b>Number of positive additional nodes (besides sentinel node)</b>		
0	452/672 (67%)*	26/69 (38%)*
1-3	168/672 (25%)*	24/69 (35%)*
≥4	52/672 (8%)*	17/69 (25%)*
Missing	1/672 (<1%)*	2/69 (3%)*

Data are median (IQR) or number (%). Some percentages do not total 100 because of rounding. \*72 patients did not have axillary lymph node dissection. †Additional metastatic lymph nodes in the axillary radiotherapy group were found in a group of patients who crossed over from axillary radiotherapy to axillary lymph node dissection and are thus not representative of the number of additional nodes in the whole group.

**Table 1: Baseline and treatment characteristics**

# Radiotherapy or surgery of the axilla after a positive sentinel node in breast cancer (EORTC 10981-22023 AMAROS): a randomised, multicentre, open-label, phase 3 non-inferiority trial



Mila Donker, Geertjan van Tienhoven, Marieke E Straver, Philip Meijnen, Cornelis J H van de Velde, Robert E Mansel, Luigi Cataliotti, A Helen Westenberg, Jean H G Klinkenbijl, Lorenzo Orzalesi, Willem H Bouma, Huub C J van der Mijle, Gard A P Nieuwenhuijzen, Sanne C Veltkamp, Leen Slaets, Nicole J Duez, Peter W de Graaf, Thijs van Dalen, Andreas Marinelli, Herman Rijna, Marko Snoj, Nigel J Bundred, Jos W S Merkus, Yazid Belkacemi, Patrick Pignat, Dominic A X Schinagl, Corneel Coens, Carlo G M Messina, Jan Bogaerts, Emiel J T Rutgers

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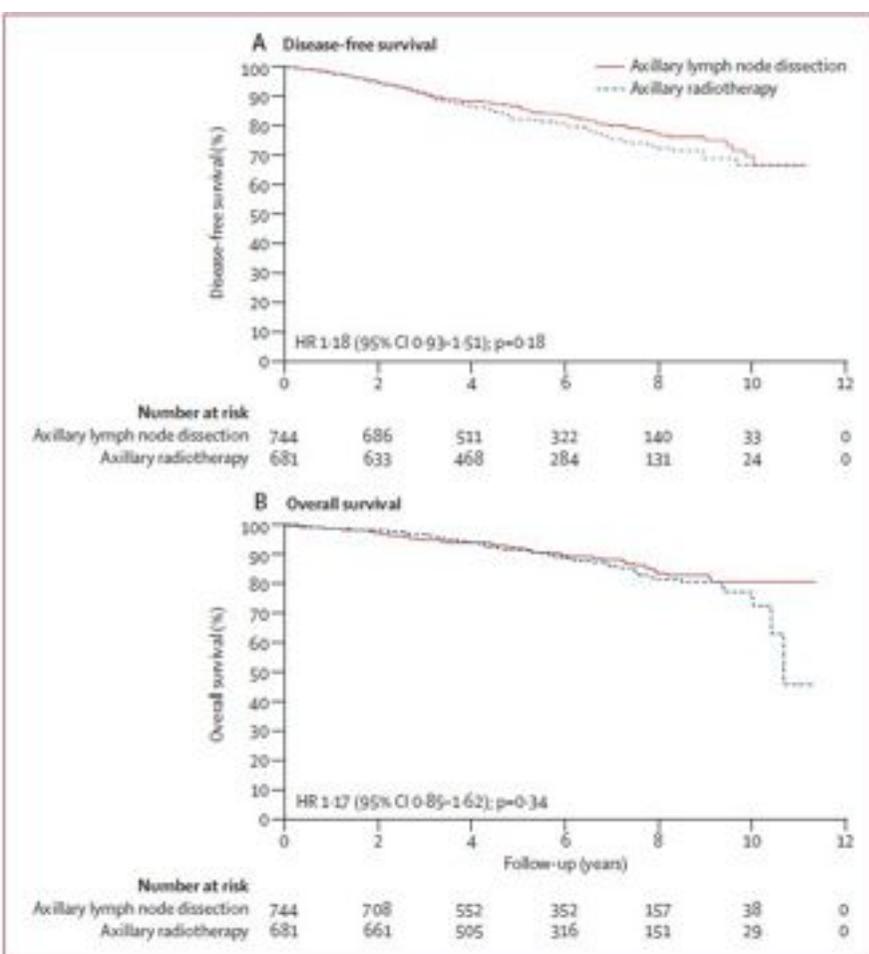


Figure 2: Disease-free survival and overall survival  
HR=hazard ratio.

	Axillary lymph node dissection	Axillary radiotherapy	p value
<b>Clinical sign of lymphoedema in the ipsilateral arm</b>			
Baseline	3/655 (<1%)	0/586 (0%)	0.25
1 year	114/410 (28%)	62/410 (15%)	<0.0001
3 years	84/373 (23%)	47/341 (14%)	0.003
5 years	76/328 (23%)	31/286 (11%)	<0.0001
<b>Arm circumference increase <math>\geq 10\%</math> of the ipsilateral upper or lower arm, or both</b>			
Baseline	33/655 (5%)	24/586 (4%)	0.497
1 year	32/410 (8%)	24/410 (6%)	0.332
3 years	38/373 (10%)	22/341 (6%)	0.080
5 years	43/328 (13%)	16/286 (6%)	0.0009

Data are n/N (%), unless otherwise specified.

Table 2: Lymphoedema

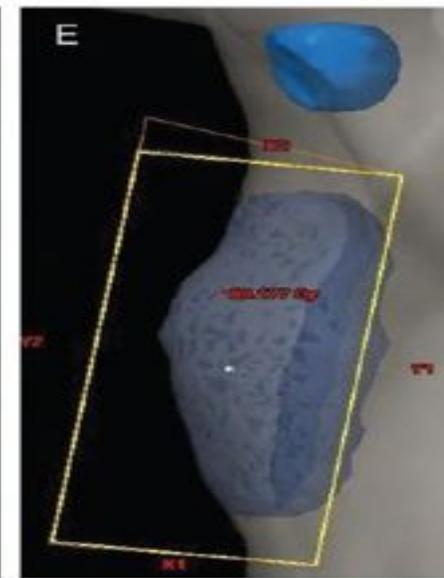
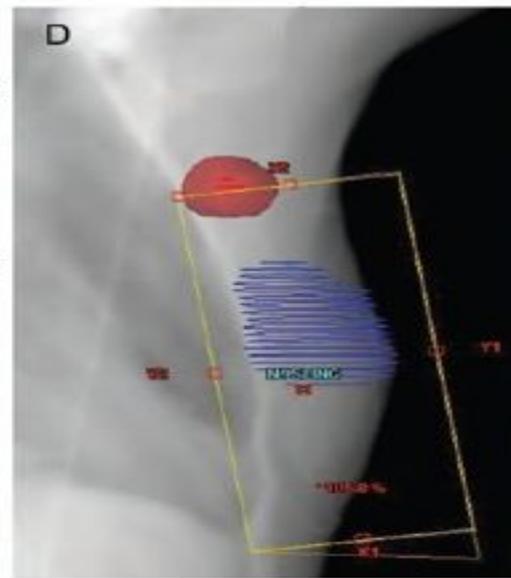
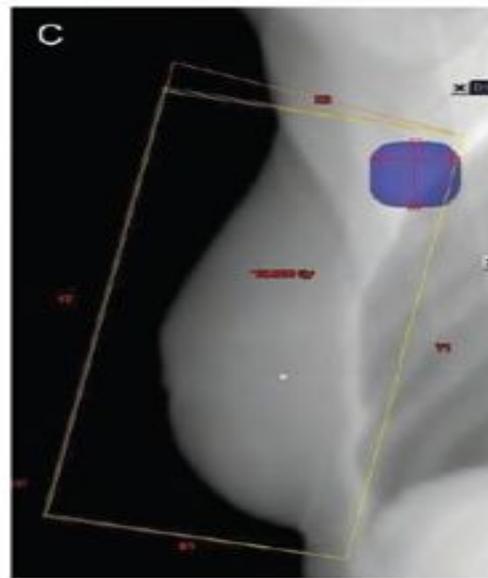
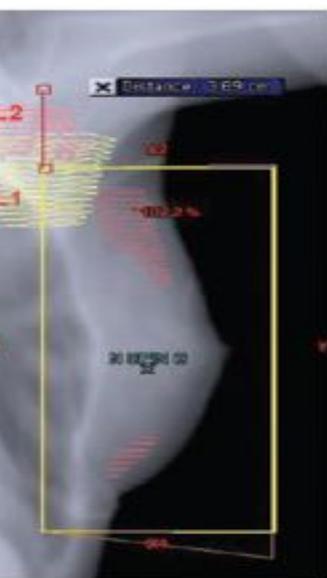
AxR  $\rightarrow$  4/744 axillary node dissection group (1)  
AxR  $\rightarrow$  7/681 axillary radiotherapy group (2)

AxR at 5 years: 0.43% group 1  
1.19% group 2

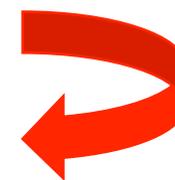
# The standard tangential fields used for breast irradiation do not allow optimal coverage and dose distribution in axillary levels I–II and the sentinel node area

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A. -P. Mège<sup>1</sup>, P. Caillet<sup>5</sup>, F. Pigneur<sup>3</sup>, T. -H. Dao<sup>3</sup>, R. Salmon<sup>6,†</sup>, E. Calitchi<sup>1</sup> & R. Bosc<sup>2</sup>

	Total (n = 109)	Group 1 (n = 18)	Group 2 (n = 34)	Group 3 (n = 57)	P value				
	Prescribed dose	(50 Gy)	(60 Gy)	(66 Gy)					
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)					
Distribution according to the total dose subgroups groups									
50 Gy <sup>a</sup>	22 (19)	23 (22)	25 (21)	21 (19)	0.005				
60 Gy <sup>b</sup>	4 (11)	10 (20)	6 (17)	1 (4)					
66 Gy <sup>c</sup>	41 (30)	42 (36)	45 (30)	40 (29)					
50 Gy <sup>a</sup>	4 (9)	6 (14)	4 (7)	6 (11)	0.04				
60 Gy <sup>b</sup>	0.3 (4)	3 (11)	0 (0)	0 (0)					
66 Gy <sup>c</sup>	7 (19)	11 (26)	5 (13)	9 (24)					
Distribution according to the tangential field size and initial tumor site									
Region	Mean dose (range)		D95 (range)		Median dose (UQ)		Median dose (LQ)		
	Level I (Gy)	Level II (Gy)	Level I (Gy)	Level II (Gy)	N	Level I (Gy)	Level II (Gy)	N	Level I (Gy)
	20 (1–57)	4 (0–46)	3 (0–53)	1 (0–8)	51 (47%)	21	5	21 (19%)	17
	33 (7–53)	11 (4–42)	11 (0–46)	5 (0–42)	12 (11%)	35	12	7 (6%)	33
	<0.0001	0.002	<0.0001	<0.0001		0.001	0.03		0.04



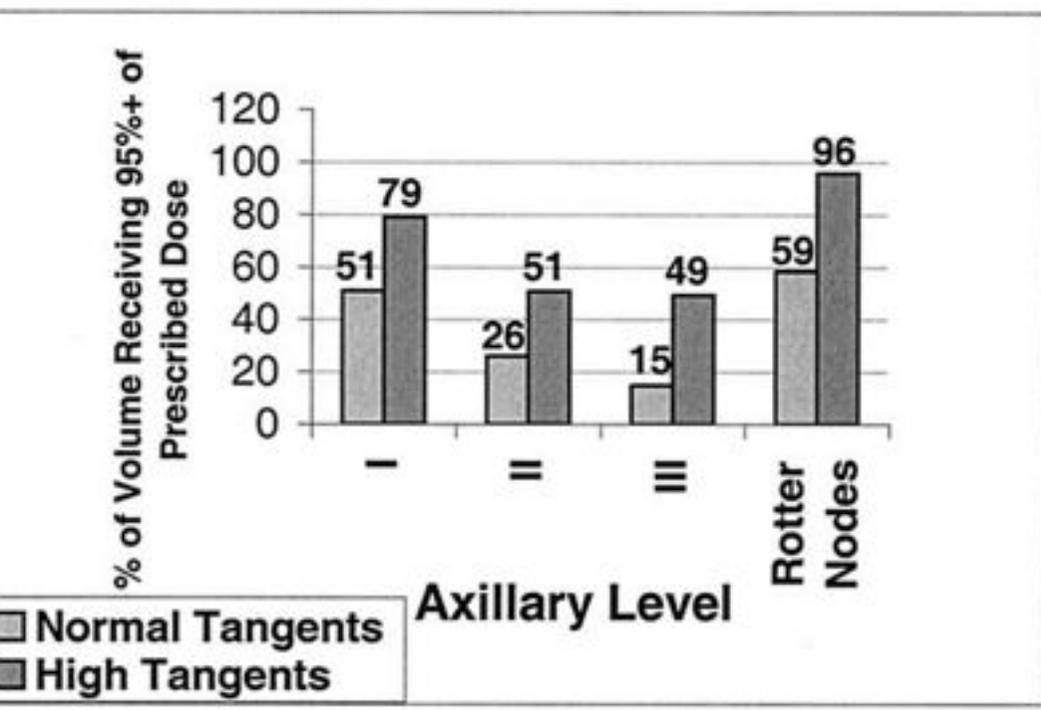
Irradiazione con campi tangenti standard



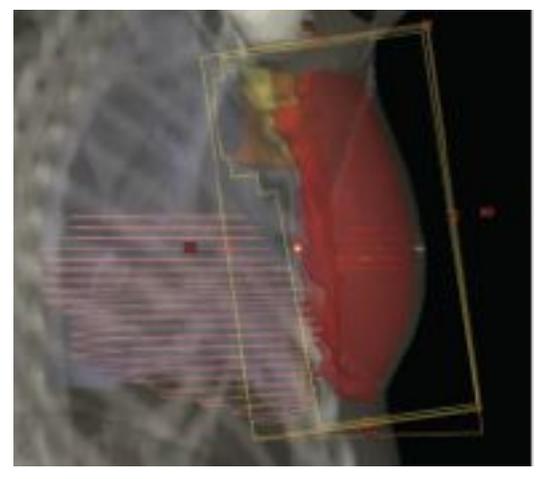
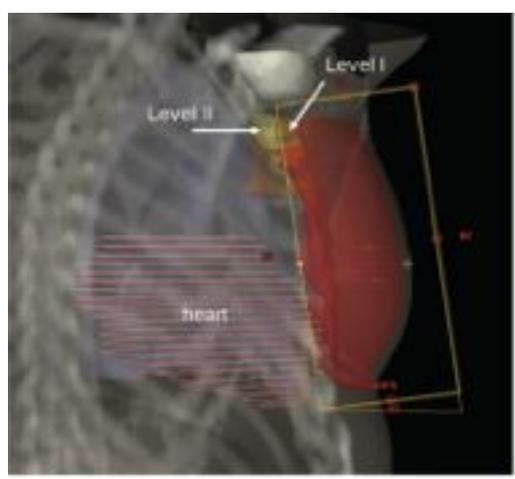
Inadeguata copertura dell'area SNLB e del I e II livello

personalize radiation fields and select the patients for whom 'minimal axillary surgery' is acceptable.

Authors	n, Axillary level	ALND	Superior border	Axillary volume (cm <sup>3</sup> )		Axillary doses (Gy)	
				I	II	I	II
Grassin et al. [11]	25	16	HTgF	50 (22–173)	23 (10–60)	32 (6–52)	26.5 (5–48)
Christei et al. [13]	35	All	STgF	–	–	39 (3–47)	21 (1–39)
Preccchia et al. [19]	15		STgF	29 (14–58)	–	25	
Leznik et al. [10]	35		HTgF	85 (24–232)	17 (4–40)		
Hashi et al. [16]	50		HTgF	48 (14.9–106.2)	8 (2.6–21.2)		
Alço et al. [14]	30		HTgF Variable <sup>a</sup>	62.46 (24–136)	11.97 (4–36)	39 (17–50)	27 (50–50)
Present study	109	ALND SLNB	STgF	15 (7–29)		20 (1–57)	4 (0–46)
			HTgF	64 (24–148)		33 (7–53)	11 (4–42)

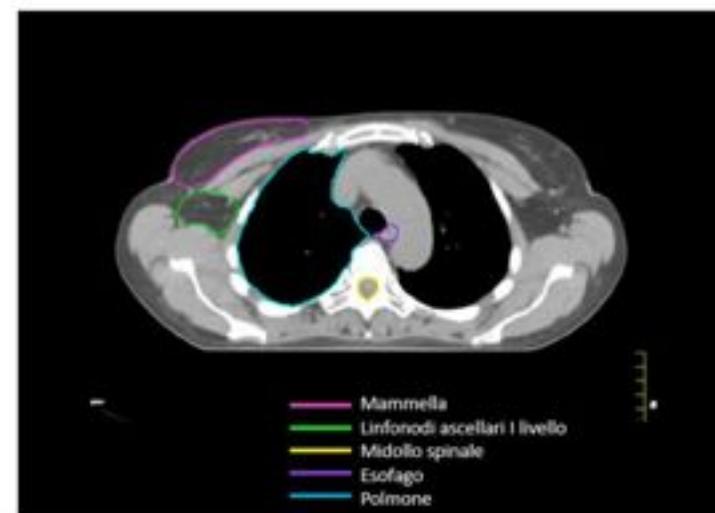
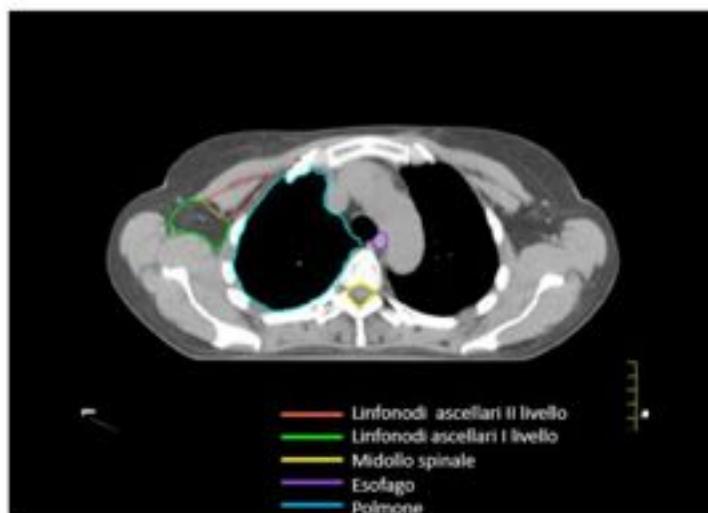
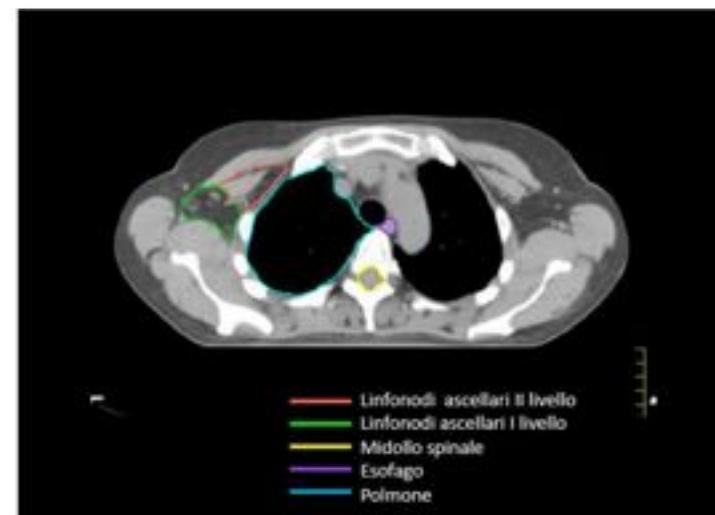
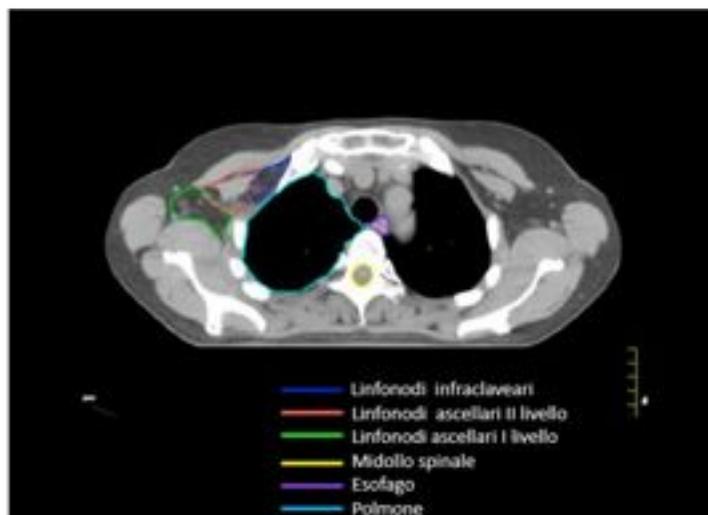


Axillary region	Mean dose of level I (range)	Mean dose of level II (range)
HTF	39.46 Gy (16.7–50.4 Gy)	26.62 Gy (4.50–50.2 Gy)
MLC-HTF	49.78 Gy (46.5–51.7 Gy)	47.12 Gy (43.17–50.1 Gy)
p-value	0.0001	0.0001



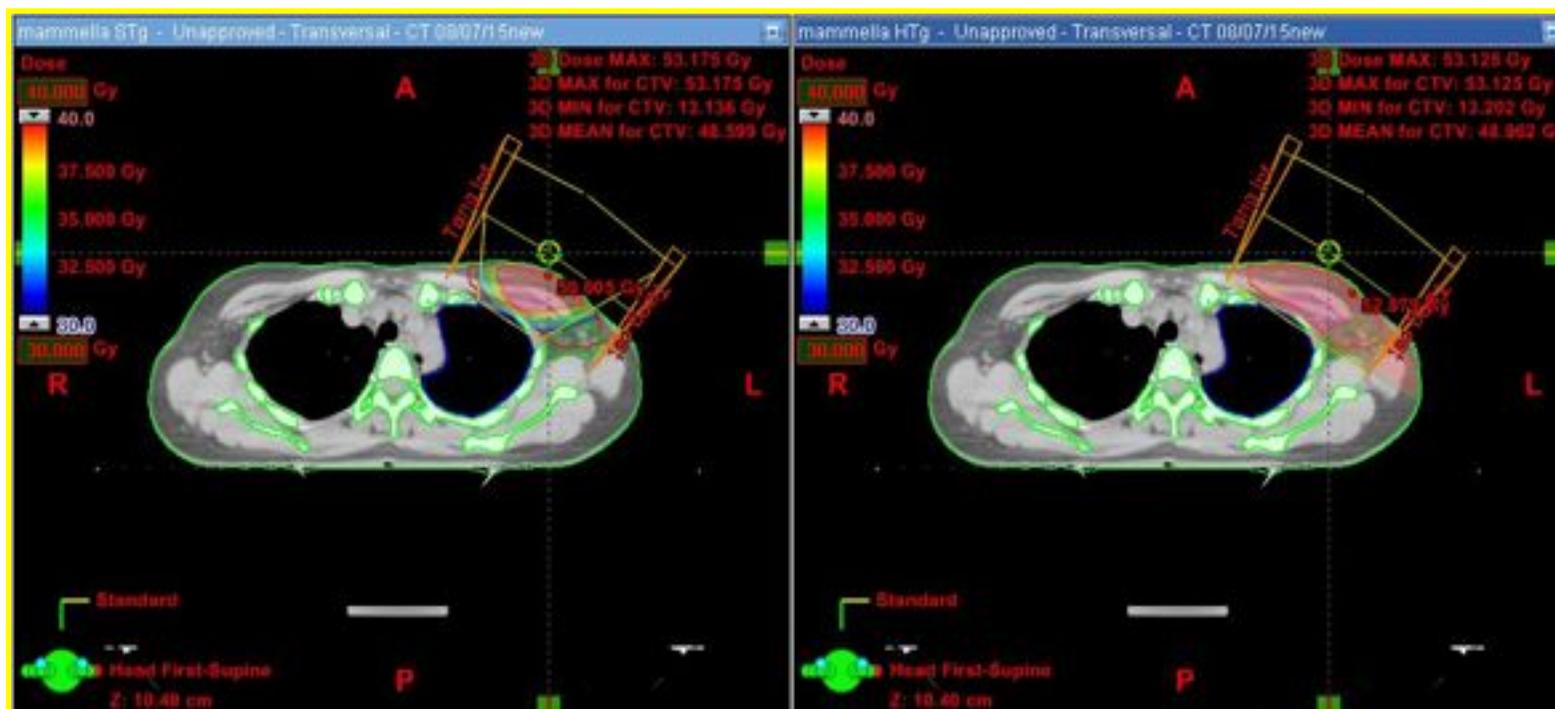
## MATERIALI E METODI

Prospettivamente sono state analizzate 216 pazienti con tumore della mammella. Per tutte le pazienti sono stati effettuati 2 piani: 1 con campi tangenti standard (STgF) ed 1 con alti campi tangenti (HTgF). Per gli STgF il limite craniale era 2 cm al di sotto della testa dell'omero, mentre negli HTgF il limite superiore coincideva con il margine inferiore della testa omerale.



# RISULTATI

SEDE N	STgF	HTgF
I Livello	26 Gy	33 Gy
II Livello	10 Gy	16 Gy
Area SLN	30 Gy	35 Gy



## CONCLUSIONI

La radioterapia della mammella con STgF fornisce una limitata copertura dell'ascella e dell'area del SLN. Queste informazioni dovrebbero essere considerate quando è prevista soltanto la radioterapia con campi tangenti nei pazienti con SLN+ senza linfadenectomia. Occorre standardizzare le tecniche radioterapiche e i limiti dei linfonodi ascellari, cercando di personalizzare il trattamento radiante e selezionare le pazienti, per le quali è accettabile un'asportazione chirurgica ascellare di minima.

**Table 1.** Suggested Approach for Radiation Field Design in Patients With Sentinel Node–Positive Disease Not Undergoing Axillary Lymph Node Dissection

Clinical Scenario	No. of Positive Sentinel Nodes	Total No. of Sentinel Nodes Sampled	Probability of Additional Nodes* (%)	Probability of Additional Nodes† (%)	Probability of Four or More Nodes Involved‡ (%)	Field Design
1.0 cm, ER positive, LVI negative	1 (IHC only)	3	3	8	< 1	Tangents only
1.8 cm, G3, ER positive, LVI negative, unifocal	1 (macro)	2	27	24	2	High tangents
2.0 cm, ER negative, LVI positive	2 (macro)	2	63	55	30	High tangents/consider full nodal treatment
4.0 cm, ER positive, multifocal, LVI negative	2 (macro)	2	77	64	40	High tangents/consider full nodal treatment
3 cm, ER negative, LVI positive, multifocal	3 (macro with ENE)	3	78	95	80	Full nodal treatment

Abbreviations: ENE, extranodal extension; ER, estrogen receptor; G, grade; IDC, infiltrating ductal carcinoma; IHC, immunohistochemistry; ILC, infiltrating lobular carcinoma; LVI, lymphovascular invasion; macro, macroscopic.

\*Based on the basis of the Memorial Sloan-Kettering Cancer Center nomogram.<sup>19</sup>

†Based on the basis of the MD Anderson Cancer Center nomogram.<sup>18</sup>

‡Z et al.<sup>23</sup>

WORK IN PROGRESS



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