ASL 1 IMPERIESE

Terapia Locoregionale del Ca Mammario Avanzato: il punto di vista dell'oncologo

Lazzaro M Repetto

ASL 1 IMPERIESE

Ca.Mammario

Malattia Locoregionale	Malattia Avanzata/ M1
Curabile	Incurabile
Guarigione	Palliazione

E’ Cambiato Qualcosa?

ASL 1 IMPERIESE

Ca Mammario Locoregionale Decision Making

- Sempre più diagnosi da Screening
  - T<1cm, RO+, HER2-
  - clinicamente non importanti (?)
  - over diagnosis (?)
- Pochi data da Studi per T1a e b
  - bassa mortalità, pochi “eventi”
- Parametri Clinico-Patologici poco utili
  - valore prognostico, ricaduta
  - valore predittivo, risposta
- Genomic Platforms
  - 35-40% change in treatment decision

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Ca Mammario Avanzato/M1 Decision Making

- pz. HER2+, mOS 56.5 mesi St. Cleopatra
- pz CRC, mOS era <6, oggi >30 mesi

- chirurgia, ecc dei pz oligometastatici
  - –CRC, Polmone, 20-25% pz vivi a 10 a.

- …e le pz mammella M1?

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VOLUME 32 · NUMBER 6 · FEBRUARY 20 2014

JOURNAL OF CLINICAL ONCOLOGY

COMMENTS AND CONTROVERSIES

Reducing Local Therapy in Patients Responding to Preoperative Systemic Therapy: Are We Outsmarting Ourselves?

Lawrence B. Marks, *University of North Carolina, Chapel Hill, NC*
Leonard R. Prosnitz, *Duke University Medical Center, Durham, NC*

VOLUME 32 · NUMBER 6 · FEBRUARY 20 2014

JOURNAL OF CLINICAL ONCOLOGY

COMMENTS AND CONTROVERSIES

Locoregional Radiotherapy in Patients With Breast Cancer Responding to Neoadjuvant Chemotherapy: A Paradigm for Treatment Individualization

Julia White, *The Ohio State University Comprehensive Cancer Center, Columbus, OH*
Eleftherios Mamounas, *MD Anderson Cancer Center Orlando, Orlando, FL*

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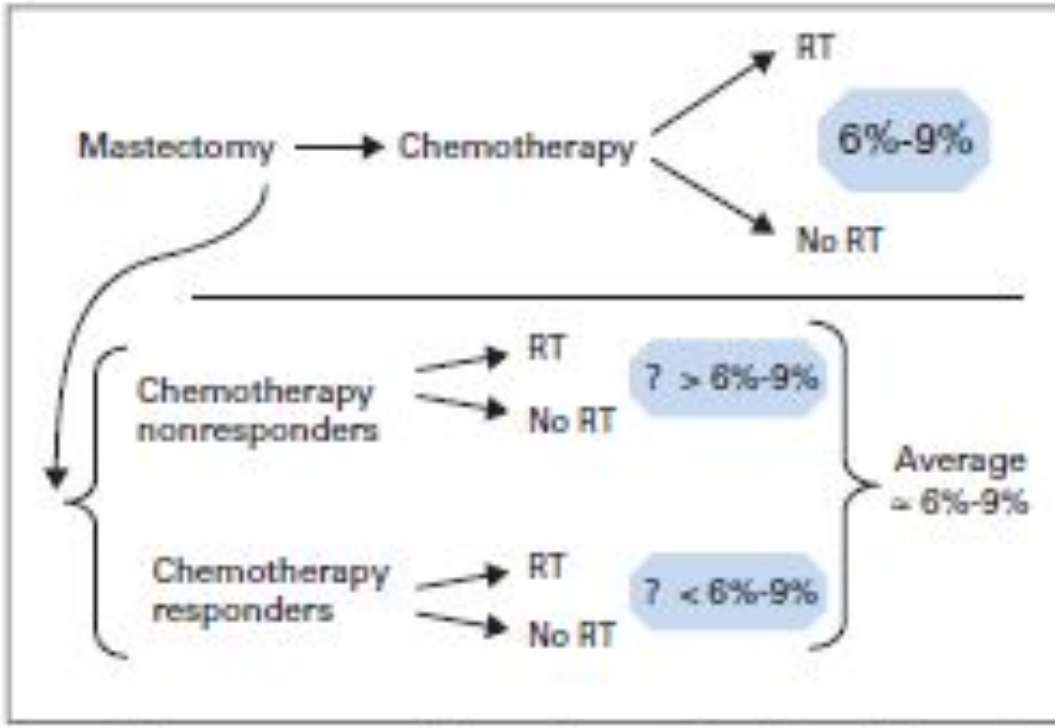

Fig 1. After mastectomy and chemotherapy, the addition of locoregional radiotherapy (RT) improves overall survival by 6% to 9% (upper panel). Among these patients, there are responders and nonresponders to chemotherapy, although we are not able to identify who they are (lower panel). If the survival benefit of RT is reduced in responders (eg, < 6% to 9%), the survival benefit of RT in nonresponders must be > 6% to 9% (because results in the two groups must average to 6% to 9%). The analogous argument can be made for nodal RT in patients undergoing breast-conservation therapy with lumpectomy and chemotherapy.

ASL 1 IMPERIESE

Ca Mammario Loc. Avanzato
Decision Making

- Personalized Medicine/Precision Medicine
  - è possibile ridurre il trattamento CH/CT/RT?
  - a quali pazienti?
  - st. in corso

- …the natural history of breast ca. is long

ASL 1 IMPERIESE

Steinauer et al. Radiation Oncology 2014, 9:126
http://www.ro-journal.com/content/9/1/126

RADIATION ONCOLOGY

RESEARCH Open Access

Radiotherapy in patients with distant metastatic breast cancer

Kirsten Steinauer[1,2], Markus Wolfram Gross[3], Dorothy Jane Huang[4], Serenella Eppenberger-Castori[5] and Uwe Güth[2,6]*

Abstract

Background: The study evaluates frequency of and indications for disease-related radiotherapy in the palliative breast cancer (BC) situation and analyzes in which phase of the palliative disease course radiotherapy was applied.

Patients & methods: 340 patients who developed distant metastatic disease (DMD) and died (i.e. patients with completed disease courses) were analyzed.

Results: 165 patients (48.5%) received palliative radiotherapy (255 series, 337 planning target volumes) as a part of palliative care. The most common sites for radiotherapy were the bone (217 volumes, 64.4% of all radiated volumes) and the brain (57 volumes, 16.9%). 127 series (49.8%) were performed in the first third of the metastatic disease survival (MDS) period; 84 series (32.8%) were performed in the last third. The median survival after radiotherapy was 10 months. Patients who had received radiation were younger compared to those who had no radiation (61 vs. 68 years, $p < 0.001$) and had an improved MDS (26 vs. 14 months, $p < 0.001$). Compared to rapidly progressive disease courses with short survival times, in cases where effective systemic therapy achieved a longer MDS (≥24 months), radiotherapy was significantly more often a part of the multimodal palliative therapy (52.1% vs. 37.1%, $p = 0.006$).

Conclusions: In a cohort of BC patients with DMD, nearly one half of the patients received radiotherapy during the palliative disease course. In a palliative therapy approach, which increasingly allows for treatment according to the principles of a chronic disease, radiotherapy has a clearly established role in the therapy concept.

Keywords: Breast cancer, Distant metastases, Palliative radiotherapy

165 paz.
RT 64% Osso
16.9% SNC
mOS dopo RT, 10 mesi
MDS RT vs noRT, 26 vs 14 mesi
RT 52.1 vs 37.1% in Paz con MDS >24 vs <24 mesi

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581 pts M1 sincrone
320 terapia locoreg. (LRT)
249/320 sola RT sul T
3yrs OS 43.4 e 26.7% LRT si/no
Vant. OS maggiore in mts visc
LRT fatt progn indip, an. multiv.

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JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Breast Cancer With Synchronous Metastases: Survival Impact of Exclusive Locoregional Radiotherapy

Romuald Le Scodan, Denise Stevens, Etienne Brain, Jean Louis Fléiras, Christine Cohen-Solal, Brigitte De La Lande, Michelle Tubiana-Hulin, Sameh Yacoub, Maya Gutierrez, David Ali, Miriam Gardner, Patricia Monsarrat, Sylviane Villette, Florence Lerebours, Jean Nicolas Munck, and Alain Labib

A B S T R A C T

Purpose
Several studies suggest that surgical excision of the primary tumor improves survival among patients with stage IV breast cancer at diagnosis. Exclusive locoregional radiotherapy (LRR) is an alternative form of locoregional treatment (LRT) in this setting. We retrospectively studied the impact of LRT on the survival of breast cancer patients with synchronous metastases.

Patients and Methods
Among 18,753 breast cancer patients treated in our institution between 1980 and 2004, 598 patients (3.2%) had synchronous metastasis at diagnosis. Demographic data, tumor characteristics, metastatic sites, and treatments were prospectively recorded. The impact of LRT on overall survival (OS) was evaluated by multivariate analysis including known prognostic factors.

Results
Among 581 eligible patients, 320 received LRT (group A), and 261 received no LRT (group B). LRT consisted of exclusive LRR in 249 patients (78%), surgery of the primary tumor with adjuvant LRR in 41 patients (13%), and surgery alone in 30 patients (9%). With a median follow-up time of 39 months, the 3-year OS rates were 43.4% and 26.7% in group A and group B (P =.00002), respectively. The association between LRT and improved survival was particularly marked in women with visceral metastases. LRT was an independent prognostic factor in multivariate analysis (hazard ratio [HR] = 0.70; 95% CI, 0.58 to 0.85; P = .0002). The adjusted HR for late death (≥ 1 year) was 0.76 (95% CI, 0.61 to 0.96; P = .02).

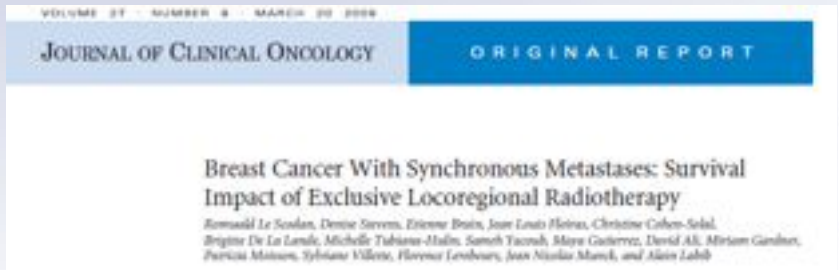
Conclusion
In our experience, LRT, consisting mainly of exclusive LRR, was associated with improved survival in breast cancer patients with synchronous metastases. Exclusive LRR may thus represent an active alternative to surgery.

ASL 1 IMPERIESE

Table 2. Univariate Analysis of Mortality (log-rank test)

Factor	Group A: LRT		Group B: No LRT		P
	3-Year OS Rate (%)	Median Survival Time (months)	3-Year OS Rate (%)	Median Survival Time (months)	
Whole population	43.4	32	26.7	21	.00002
Chemotherapy alone	32	23	6.7	9	.00001
HT ± CT	46.1	35	32.3	26	.002
CT ± HT	47.2	35	23.1	18	.00001
Bone metastases only	56	42	49.1	34	NS
Visceral metastases	34.2	25	17.8	13	.0005
Multiple sites of metastases	26.7	21	12.3	13	.003

Abbreviations: LRT, locoregional treatment; OS, overall survival; CT, chemotherapy; HT, hormonal treatment; NS, not significant.


VOLUME 27 · NUMBER 8 · MARCH 20 2009

JOURNAL OF CLINICAL ONCOLOGY | ORIGINAL REPORT

Breast Cancer With Synchronous Metastases: Survival Impact of Exclusive Locoregional Radiotherapy

Romuald Le Scodan, Denise Stevens, Etienne Brain, Jean Louis Fléteau, Christine Cohen-Solal, Brigitte De La Lande, Michelle Tubiana-Hulin, Sameh Taoufi, Maya Gutierrez, David Ali, Miriam Gardner, Patricia Maisons, Sylviane Villette, Florence Lerebours, Jean Nicolas Marck, and Alain Labib

Table 3. Multivariate Analysis of Overall Survival, Cox Model (n = 564)

Characteristic	Hazards Ratio for Death	95% CI	P
Multiple sites			.00005
No	1		
Yes	1.60	1.30 to 2.00	
Medical treatment			.00001
CT alone	1		
HT ± CT	0.53	0.40 to 0.70	
LRT			.0002
No	1		
Yes	0.70	0.58 to 0.85	
Age, years			.003
24-54	1		
55-94	1.27	1.10 to 1.60	
Visceral metastases			.03
No	1		
Yes	1.27	1.00 to 1.60	
Clinical node stage			.0003
N0	1		
N1-3	1,50	1.20 to 1.85	

Abbreviations: CT, chemotherapy; HT, hormonal treatment; LRT, locoregional treatment.

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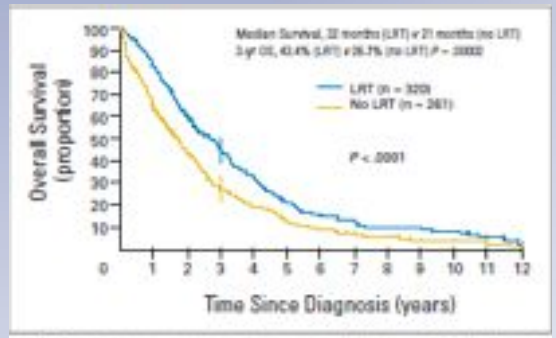

Fig 1. Survival curves according to locoregional treatment (LRT) in the entire population. OS, overall survival.

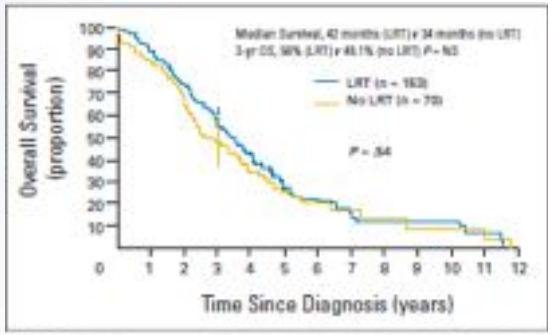

Fig 3. Survival curves according to locoregional treatment (LRT) for patients with bone metastases alone. OS, overall survival.

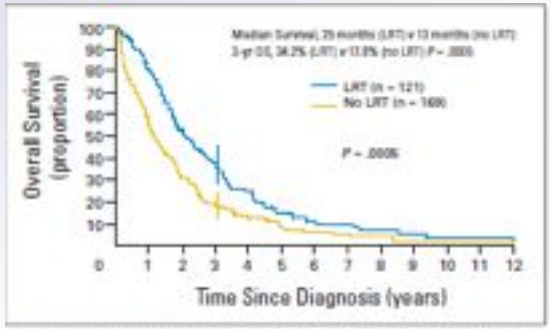

Fig 2. Survival curves according to locoregional treatment (LRT) for patients with visceral metastases. OS, overall survival.

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In conclusion, our study suggests that LRT of the primary breast tumor and regional lymphatics, mainly consisting of exclusive LRR, improves the survival of women with metastatic breast cancer at diagnosis and especially women with features of poor prognosis. Thus, LRR may represent an effective alternative to surgery. Well-designed prospective studies, including LRR as the only LRT, are needed to re-evaluate treatment of the primary breast tumor in patients with metastases at diagnosis and to identify patients who are most likely to benefit

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San Antonio Breast Cancer Symposium - Cancer Therapy and Research Center at UT Health Science Center – December 10-14, 2013

Surgical Removal Of Primary Tumor And Axillary Lymph Nodes In Women With Metastatic Breast Cancer At First Presentation : A Randomized Controlled Trial

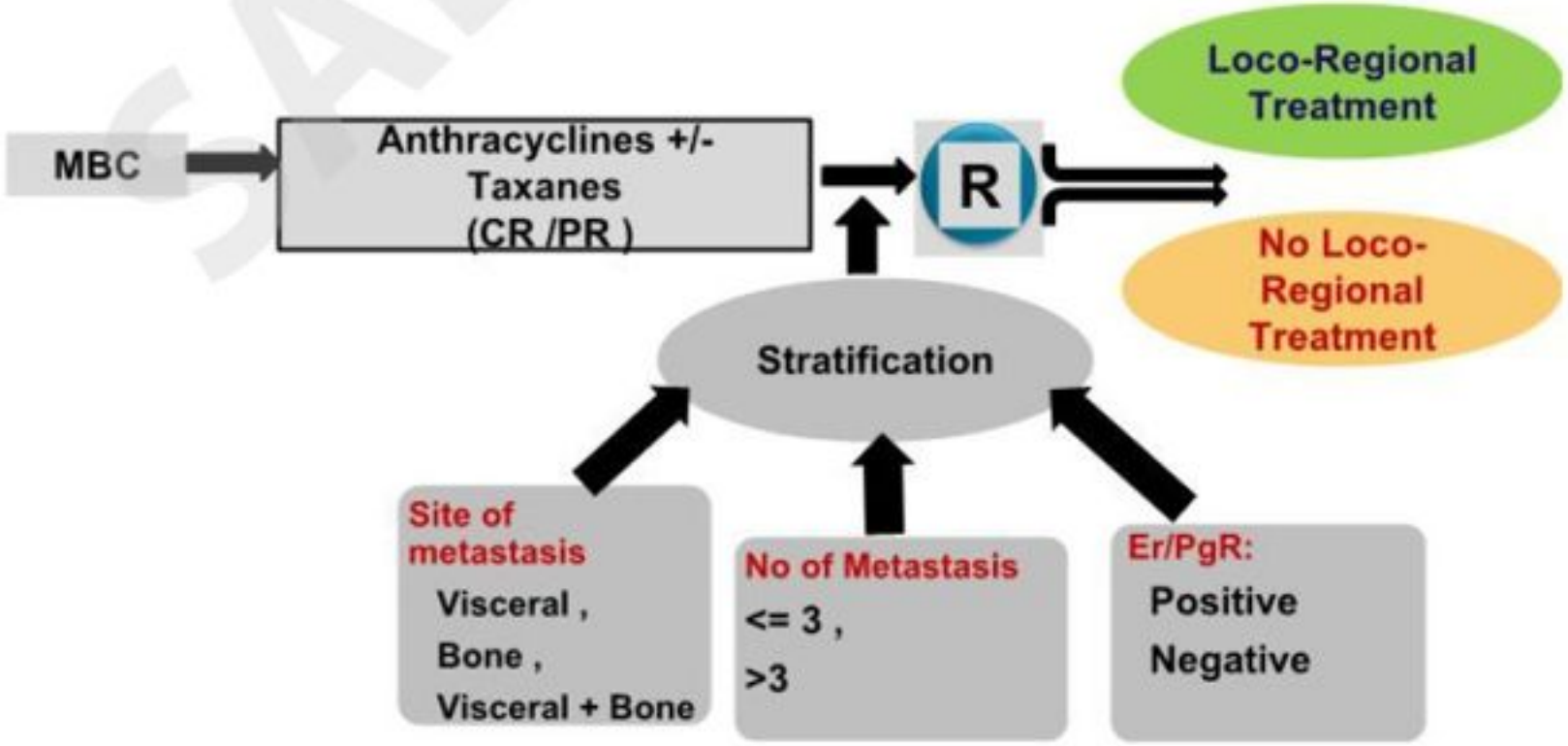
PI: R A Badwe

Professor Surgical Oncology(Breast)

Tata Memorial Centre
Mumbai , India

Co-Investigators
V Parmar, R Hawaldar , N Nair, R Kaushik, S Siddique, A Nawle, A Budrukkar, I Mittra, S Gupta

TRIAL SCHEMA



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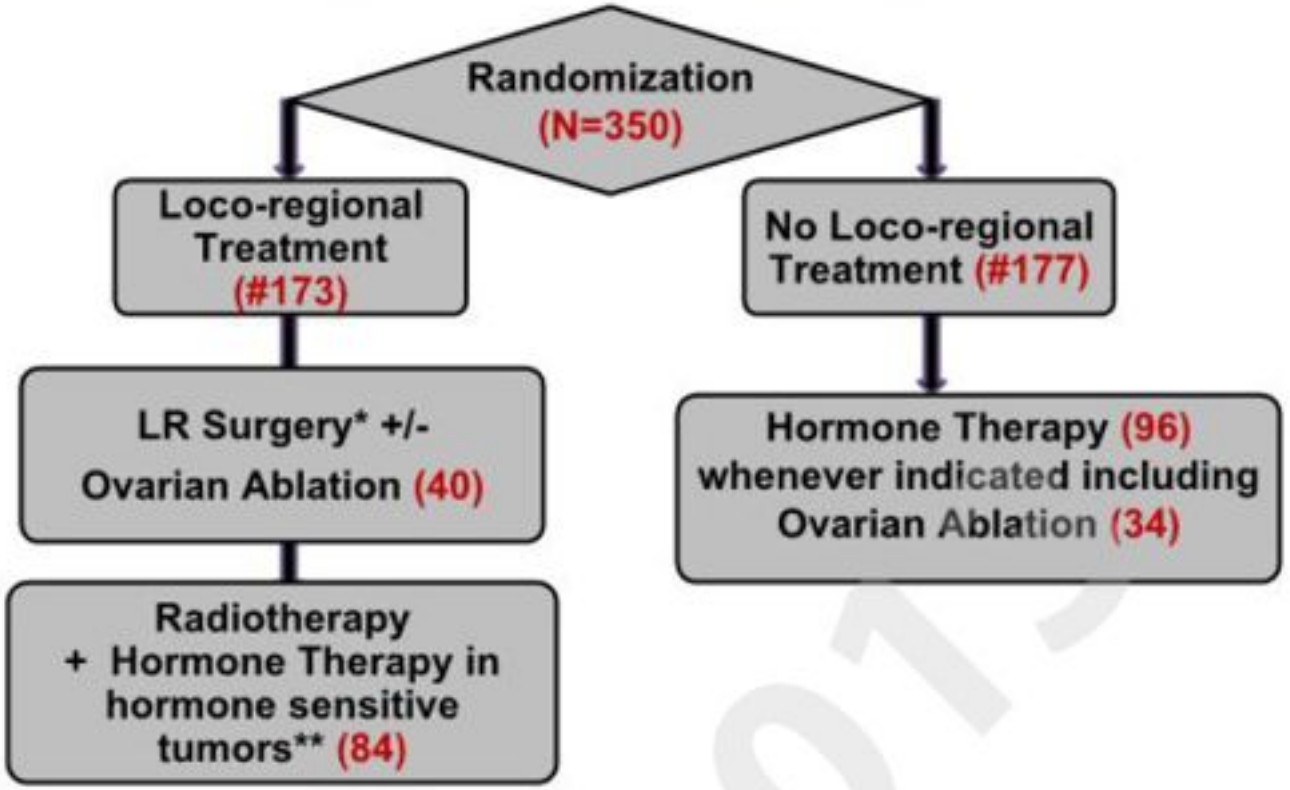
TRIAL SCHEMA



*Loco-regional Therapy : BCT / MRM with supraclavicular lymph node clearness whenever indicated
** Tamoxifen in pre menopausal women and AI in Post menopausal women/ post Oophorectomy in pre menopausal women

STRATIFICATIONS

	NO LRT (#177) N (%)	LRT (#173) N (%)	TOTAL
Site of Metastasis			
Bone	50 (50.0)	50 (50.0)	100
Visceral	77 (50.7)	75 (49.3)	98
Bone + Visceral	50 (51.0)	48 (49.0)	152
No. of Metastasis			
<= 3	45 (50.6)	44 (49.4)	89
>3	132 (50.6)	129 (49.4)	261
ER/PgR			
Positive	106 (51.0)	102 (49.0)	208
Negative	71 (50.0)	71 (50.0)	142
Age (Median)	47	48	47
Menopausal status			
Pre	88 (54.3)	74 (45.7)	162
Post	89 (47.3)	99 (52.7)	186

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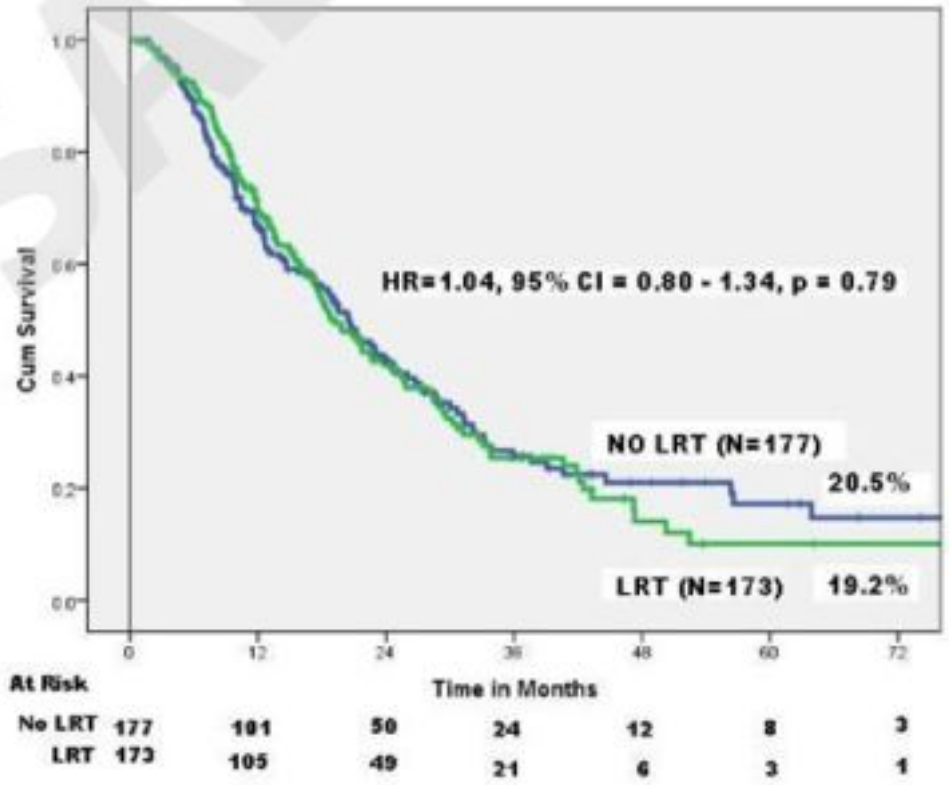
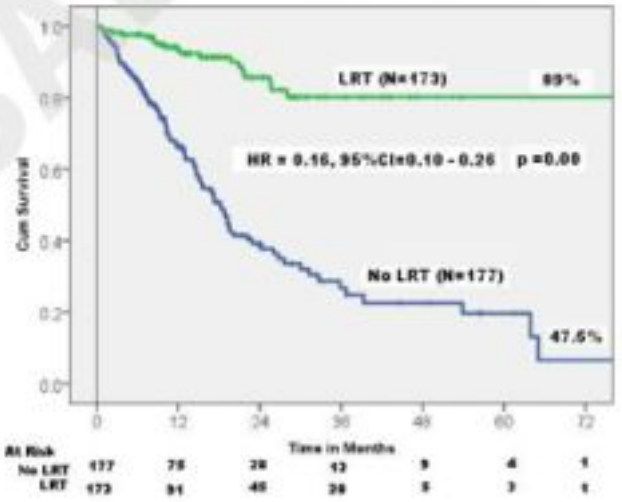
OVERALL SURVIVAL



FIRST PROGRESSION - LOCAL



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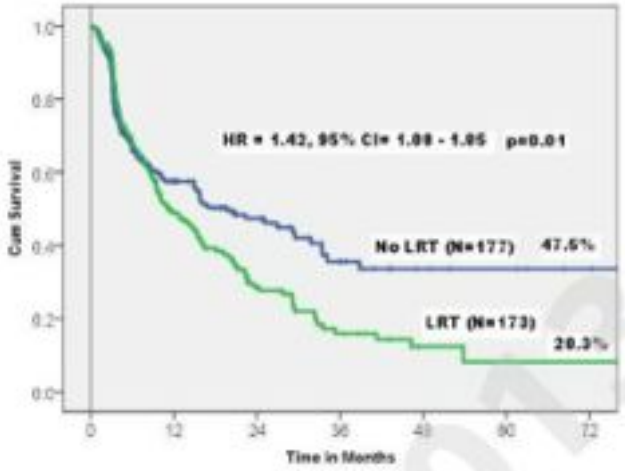
FIRST PROGRESSION - DISTANT



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Early follow up of a randomized trial evaluating resection of the primary breast tumor in women presenting with de novo stage IV breast cancer; Turkish Study (Protocol MF07-01)

Atilla Soran, Vahit Ozmen, Serdar Ozbas, Hasan Karanlık, Mahmut Muslumanoglu, Abdullah Igci, Zafer Canturk, Zafer Utkan, Cihangir Ozaslan, Turkkan Evrensel, Cihan Uras, Erol Aksaz, Aykut Soyder, Umit Ugurlu, Cavit Col, Neslihan Cabioğlu, Betül Bozkurt, Temel Dagoglu, Ali Uzunkoy, Mustafa Dulger, Neset Koksal, Omer Cengiz, Bahadir Gulluoglu, Bulent Unal, Can Atalay, Emin Yıldırım, Ergun Erdem, Semra Salimoglu, Atakan Sezer, Ayhan Koyuncu, Gunay Gurleyik, Haluk Alagol, Nalan Ulufi, Uğur Berberoğlu, Elizabeth D Kennard, Sheryl Kelsey, Barry Lembersky

On behalf of the Turkish Federation of Societies for Breast Diseases

ClinicalTrials.gov identifier number:NCT00557986.

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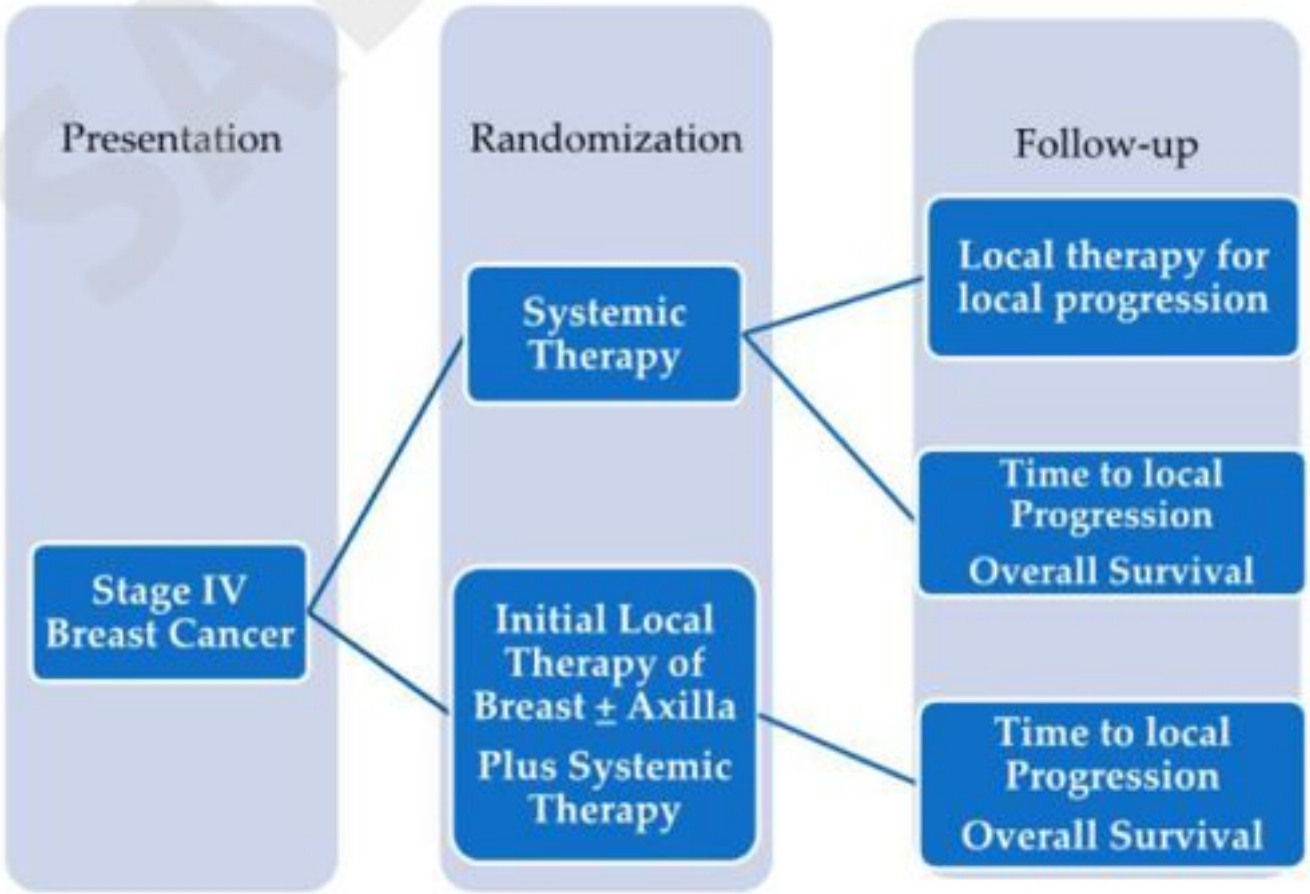
Design MF07-01



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Baseline Characteristics (Metastasis)

	Surgery %(140)	Systemic Tx %(138)	P
METASTASIS SITE			ns
1 organ	76 (106)	65 (89)	
>1 organ	24 (34)	35 (49)	
Bone only	52 (73)	40 (55)	
Bone +others	24 (33)	27 (37)	
others (No bone)	24 (34)	33 (46)	
Solitary Bone	24 (33)	15 (20)	
Multiple Bone	29 (40)	25 (35)	
Solitary Pulmonary or Liver	9 (13)	12 (16)	
Multiple Pulmonary or Liver	9 (13)	12 (16)	

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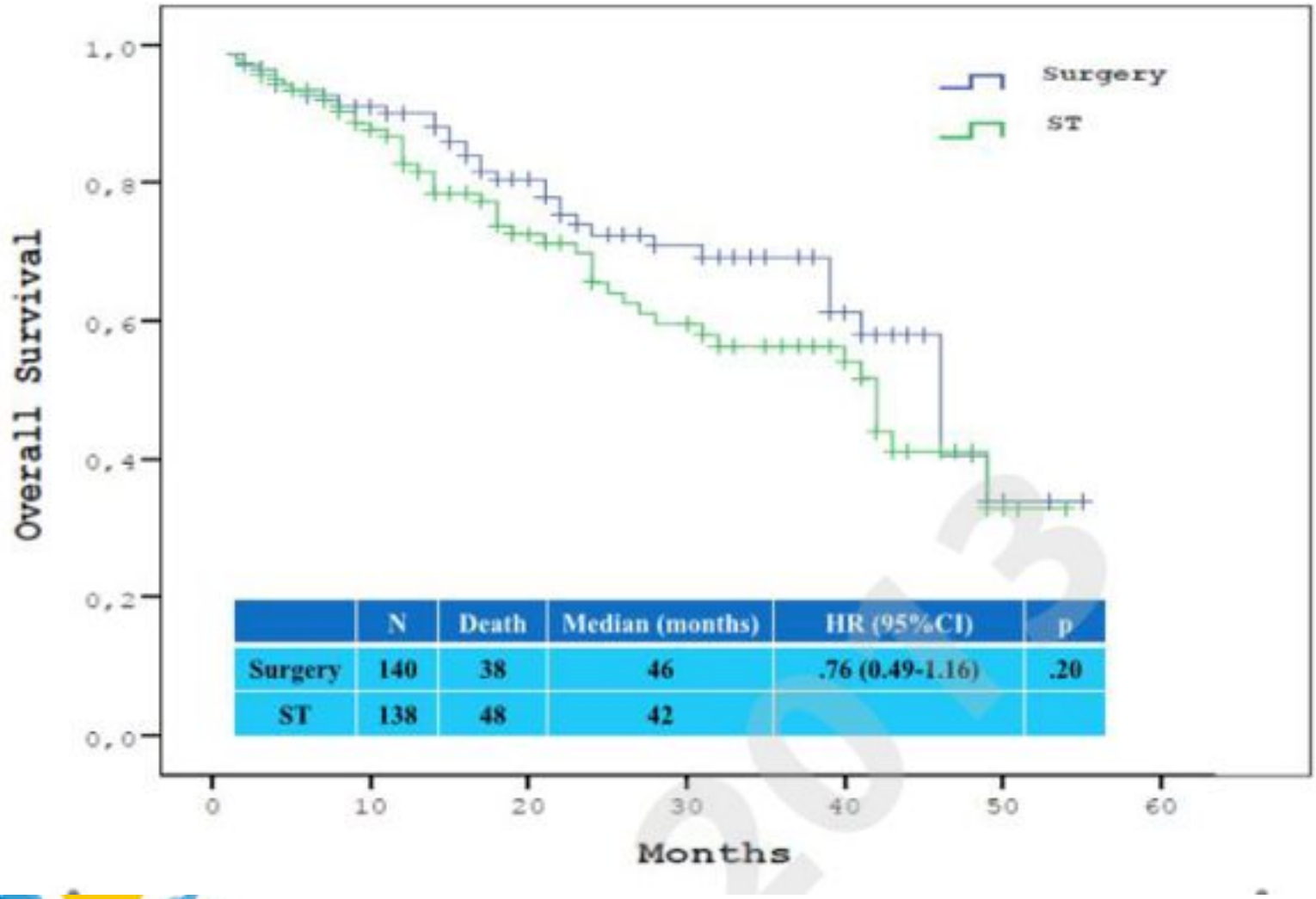

	N	Death	Median (months)	HR (95%CI)	p
Surgery	140	38	46	.76 (0.49-1.16)	.20
ST	138	48	42		

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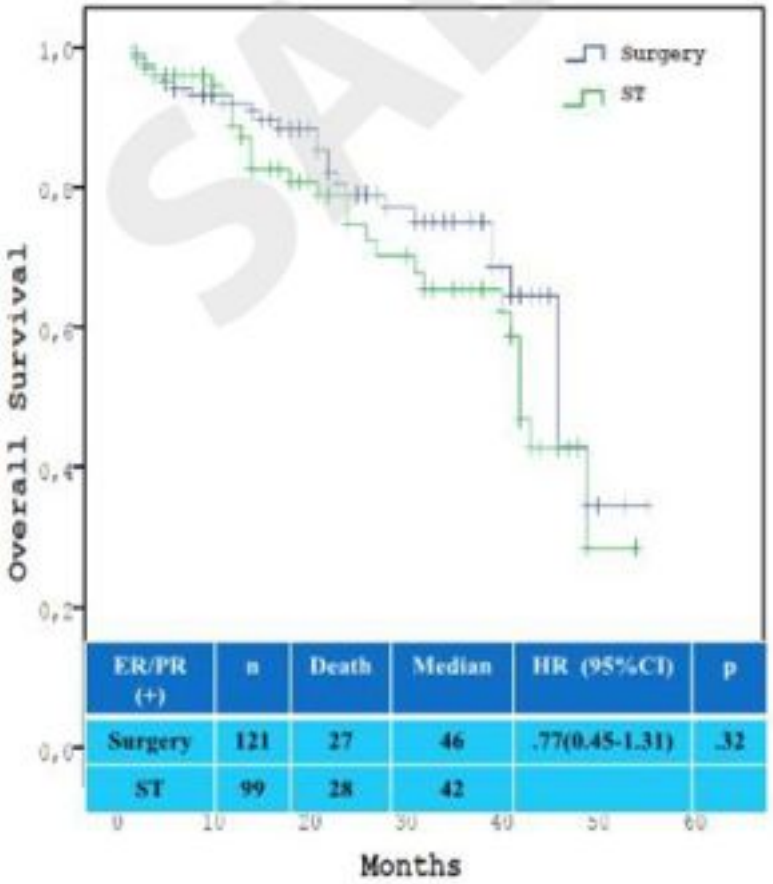
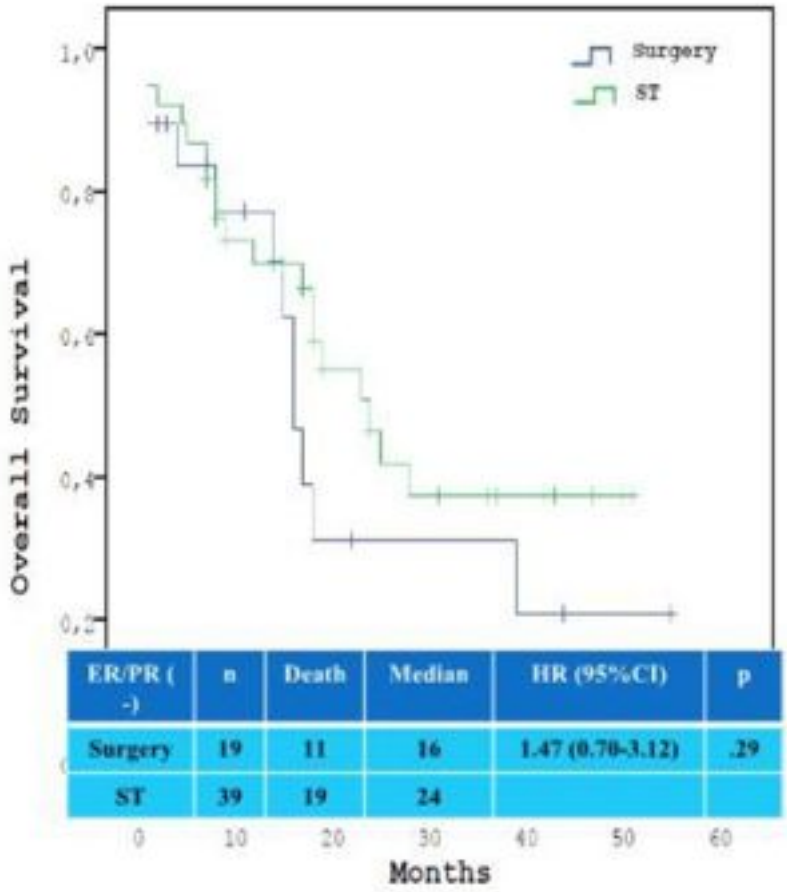
ER/PR Positive



ER/PR (+)	n	Death	Median	HR (95%CI)	p
Surgery	121	27	46	.77(0.45-1.31)	.32
ST	99	28	42		

ER/PR Negative



ER/PR (-)	n	Death	Median	HR (95%CI)	p
Surgery	19	11	16	1.47 (0.70-3.12)	.29
ST	39	19	24		

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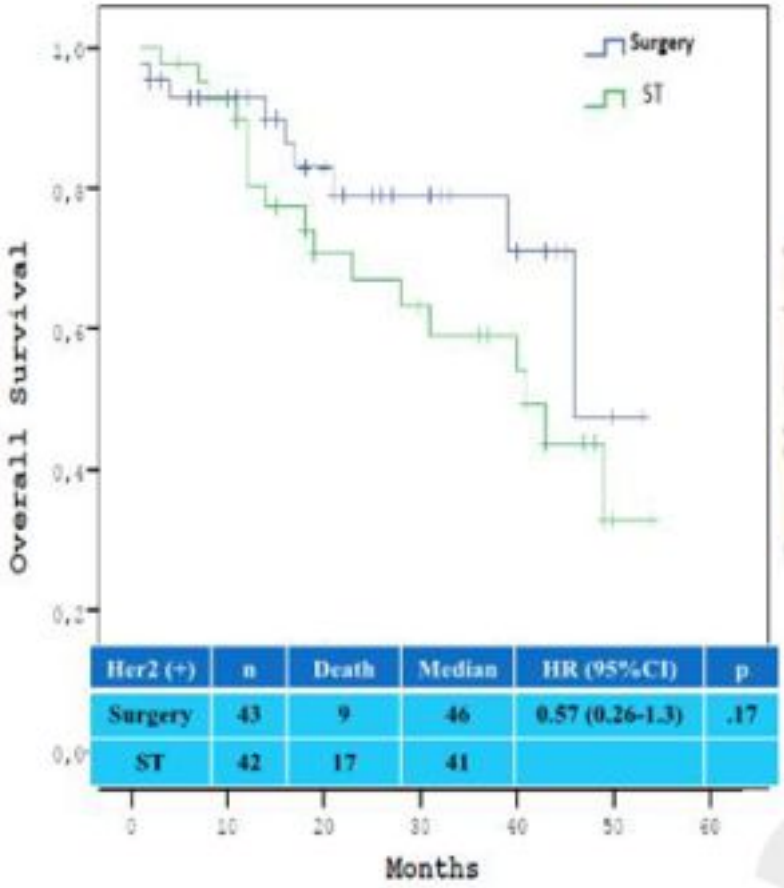
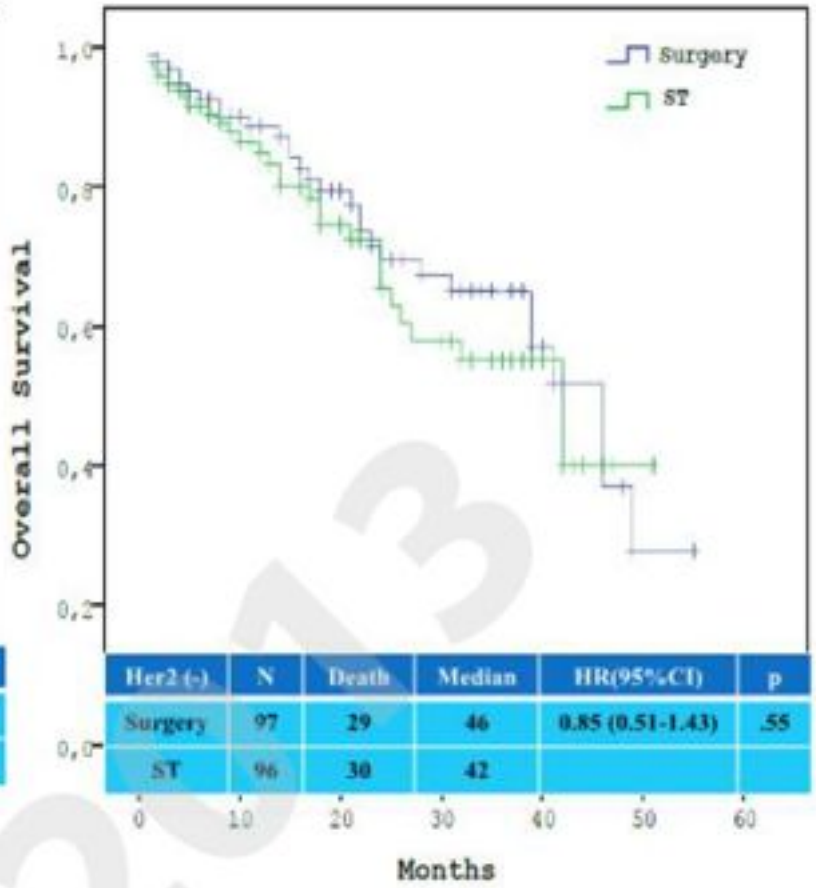
Her2 Positive



Her2 (+)	n	Death	Median	HR (95%CI)	p
Surgery	43	9	46	0.57 (0.26-1.3)	.17
ST	42	17	41		

Her2 Negative



Her2 (-)	N	Death	Median	HR(95%CI)	p
Surgery	97	29	46	0.85 (0.51-1.43)	.55
ST	96	30	42		

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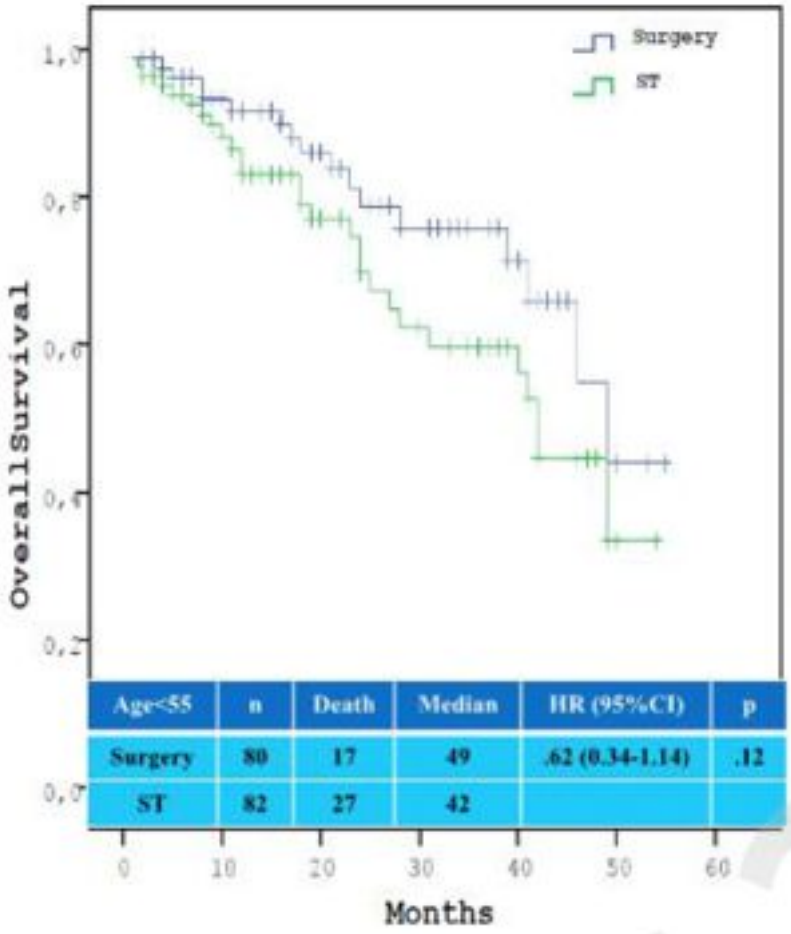
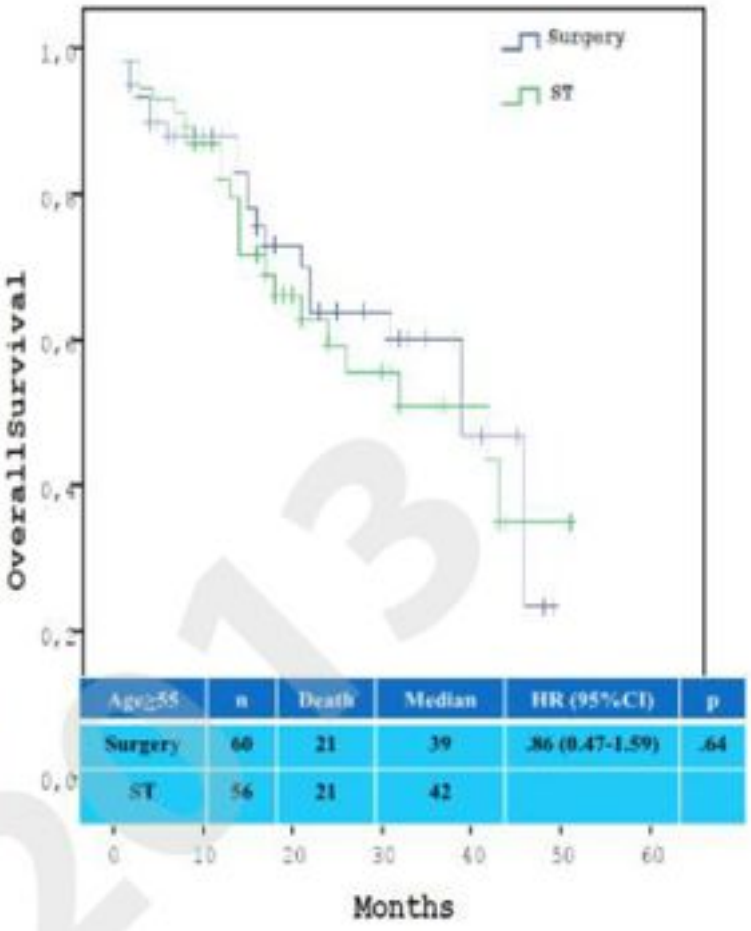
Age<55



Age<55	n	Death	Median	HR (95%CI)	p
Surgery	80	17	49	.62 (0.34-1.14)	.12
ST	82	27	42		

Age ≥55



Age≥55	n	Death	Median	HR (95%CI)	p
Surgery	60	21	39	.86 (0.47-1.59)	.64
ST	56	21	42		

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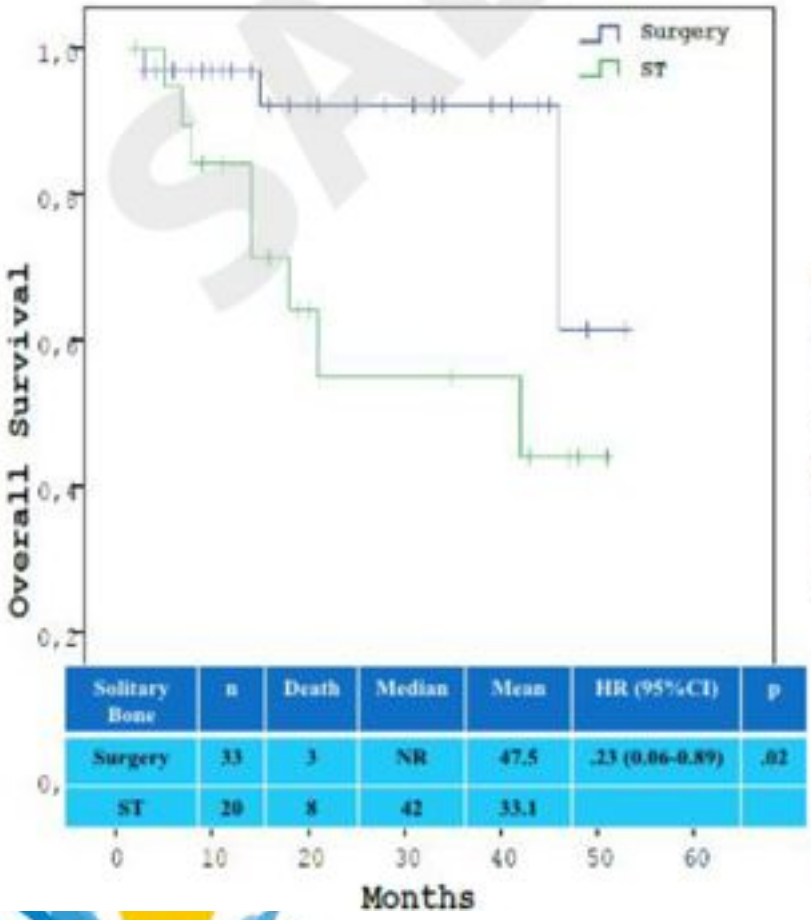
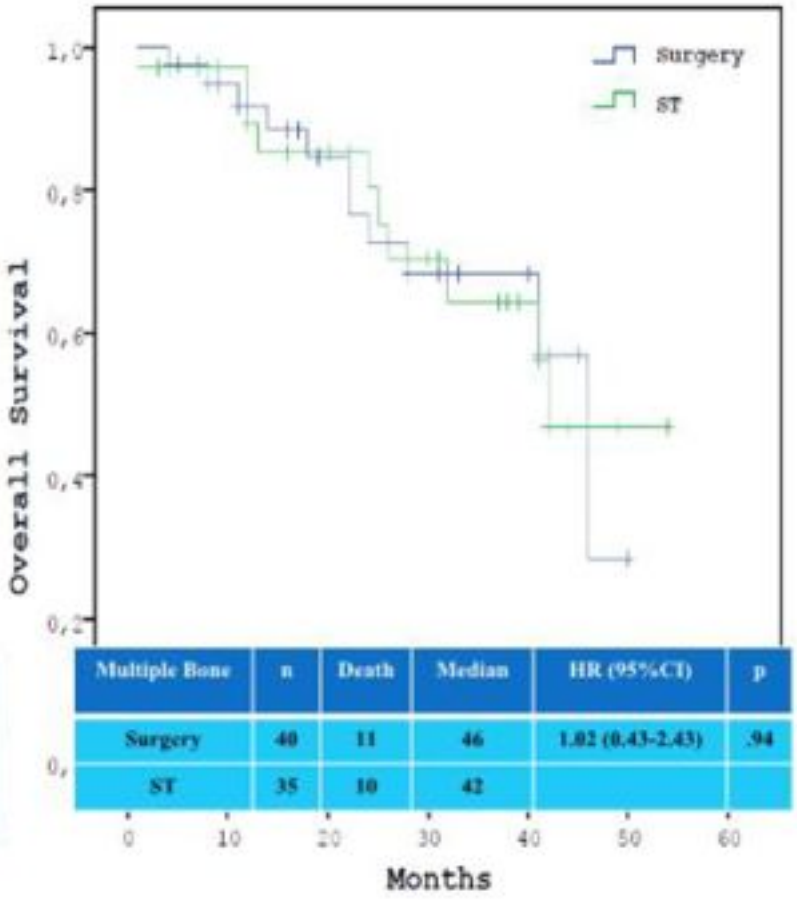
Solitary Bone Met.



Solitary Bone	n	Death	Median	Mean	HR (95%CI)	p
Surgery	33	3	NR	47.5	.23 (0.06-0.89)	.02
ST	20	8	42	33.1		

Multiple bone Met.



Multiple Bone	n	Death	Median	HR (95%CI)	p
Surgery	40	11	46	1.02 (0.43-2.43)	.94
ST	35	10	42		

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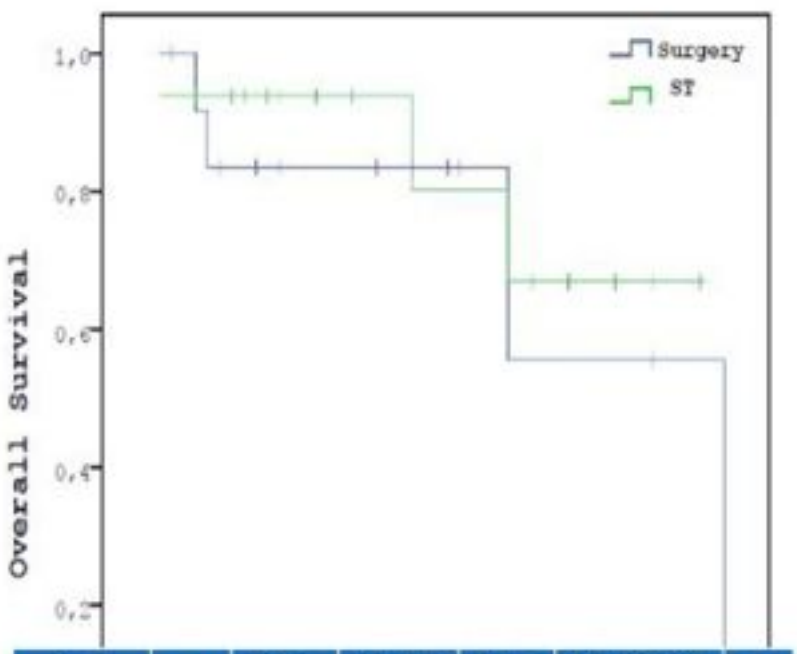
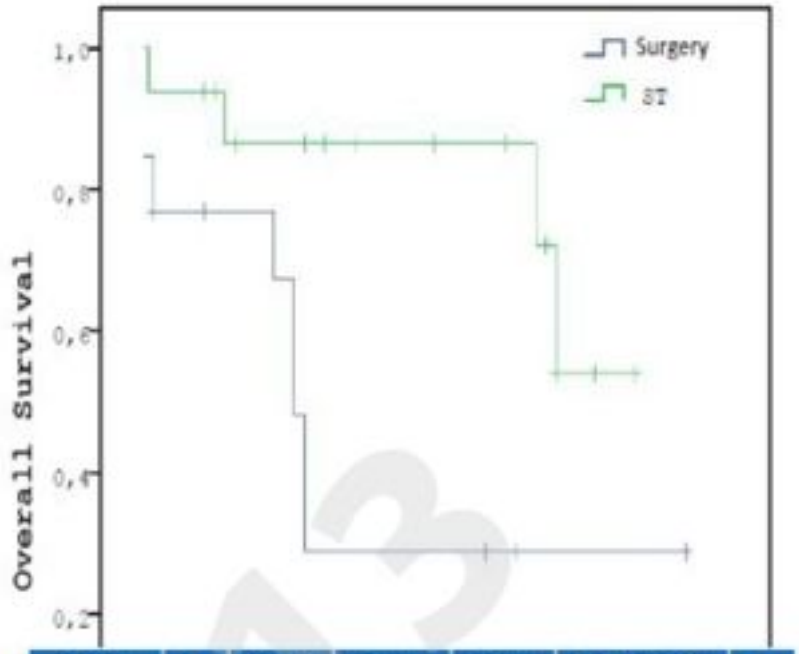
Solitary Liver/Pulmonary Met.



Single	n	Death	Median	Mean	HR (95%CI)	p
Surgery	13	4	49	36.7	1.44 (0.29-7.23)	.64
ST	16	3	NR	38.8		

Mutiple Liver/Pulmonary Met.



Multi.	n	Death	Median	Mean	HR (95%CI)	p
Surgery	13	8	16	23.8	3.85 (1.12-13.25)	.02
ST	16	4	NR	41.1		

Conclusions

- **No statistically different difference in overall survival at early follow-up**
  - Longer follow-up necessary
  - *LR Progression was 5 times higher in ST group (Surgery 1 (% 0.7) vs ST 5 (3.6%)*
- **Potentially important subgroup differences**
  - Bone only metastases trending toward prolonged survival
  - Patients with solitary bone metastases had prolonged survival
  - Younger patients (<55)have a trend toward improved survival with initial surgery
  - Patients with aggressive phenotypes appear to derive less benefit from early surgical intervention
  - Multiple Liver and/ or pulmonary metastases had a significant worse prognosis with initial surgery

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De Novo Stage IV Breast Cancer: Breast Conserving Resection of the Primary Tumor?

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Multiple retrospective reviews completed over the past decade suggest a survival advantage with resection of the intact primary tumor in women with metastatic breast cancer. However, these reviews are not without bias, and recently completed randomized trials do not support a significant survival benefit, although local control benefits may exist. Completion of ongoing trials is needed to reach a definitive conclusion regarding the merit of

TABLE I. Use of Breast Conserving Surgery in Retrospective Studies

		Mean or median age (years)		T1-2%		Primary site therapy (N)	
Author	N	Surgery	None	Surgery	None	BCS	With RT
Babiera	224	50	55	40	43	39	9
Bafford	147	51.4	51.5	56	45	21	NR
Blanchard	395	63.3	57.1	19[a]	7[a]	53	1
Fields	409	55.9	58.9	44	27	61	NR
Gnerlich	9,734	62	66	58	27	1,844	1,875[b]
Hazard	111	52.7	57.5	21	27	17	30[b]
Khan	16,023	62.5	62.5	61		3,513	NR
Le Scodan[c]	581	60.2	61.2	36	28	36	27
Leung	157	54.0	59.6	61[d]	48[b]	NR	NR
Nguyen[c]	733	58	61	16[a]	9[c]	49	21
Rapiti	300	61.8	71.6	39	25	40	11
Ruiterkamp	728	60.2	64.8	60	37	85	98[b]
Shien	344	53 (<50)	65 (<50)	25	22	4	0
Rashaan	171	69 (<50)	NR	49	NR	11	NR
Pathy	375	49	50	10	10	6	NR
Perez-Fildago	208	55.9	59.2	12[a]	6 (T1)	10	NR
Dominici	551	53.4	56.3	NR	NR	NR	NR
Neuman	186	53	58	NR	NR	41	9[b]
McGuire	566	60	52.5	NR[e]	NR[e]	56	30

[a]T1 only (T2-4 grouped together).
[b]RT numbers not reported separately for breast conservation and post-mastectomy therapy.
[c]Local therapy includes primary RT without surgery.
[d]Includes Tx.
[e]T1-2 fraction not reported but median size 4 cm.

ASL 1 IMPERIESE

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TABLE II. Randomized Clinical Trials Addressing Impact of Local Therapy for the Primary Tumor

Country	Trial number	Accrual period	N	Initial therapy	Radiotherapy	Primary endpoint
India	NCT00193778	2005–2012	350	Adriamycin, cytoxan, 5-FU	If indicated	Time to progression
Japan	JCOG 1017	2011–2016	410	Systemic therapy	Not addressed	Survival
USA and Canada	NCT01242800	2011–2016	880	Systemic therapy	Per standards for stage I–III	Survival
Turkey	NCT00557986	2008–2012	281	Surgery	For breast conservation	Survival
Netherlands	NCT01392586	2011–2016	516	Surgery	For positive margins or palliation	2-year survival
Austria	NCT01015625	2010–2019	254	Surgery	Per standards for stage I–III	Survival

Review of the retrospective data suggests that there may be a survival advantage to locoregional therapy in women with metastatic breast cancer, which is not confirmed by two unpublished randomized trials.

surgery and radiation carry some risk, locoregional therapy for the primary tumor should be offered to patients only with full disclosure of the lack of evidence of a survival benefit, and the offer of clinical trial participation if one is available. If primary tumor resection is agreed upon after full disclosure, every effort should be made to maximize the use of breast conserving resection; the evidence supporting the use of post-operative radiotherapy is weak, at best, and cannot be recommended at this time. Primary radiotherapy can be considered with the same caveats as surgical resection, particularly if the surgical procedure required would be mastectomy.

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Breast Care

Review Article

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Primary Metastatic Breast Cancer: The Impact of Locoregional Therapy

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LRT, può essere detrimentale
Solo nella paziente sintomatica sul T
Meglio in Studi Clinici

Summary

The impact of treatment for the primary tumor on distant metastases and survival in primary metastatic breast cancer patients is controversial. Previous retrospective studies and meta-analyses suggested a survival benefit for the removal of the primary tumor. Early follow-up data from 2 prospectively randomized trials presented at San Antonio Breast Cancer Symposium 2013 could not confirm this. Only a very small subgroup of patients with solitary bone metastases seemed to profit from surgery, while patients with multiple visceral metastases showed a worse prognosis with initial surgery. There are no studies available with the primary aim to investigate the impact of axillary lymph node surgery or locoregional radiotherapy on the survival of stage IV breast cancer patients. Based on current data, locoregional treatment in primary metastatic breast cancer should not be recommended in patients with asymptomatic primary tumor as a matter of routine. More solid conclusion of the impact of primary tumor treatment in stage IV breast cancer patients on their prognosis will be reached with the completion of the ongoing prospectively randomized trials. Until these studies are completed, locoregional therapy, which can provoke additional morbidity in a metastatic setting with limited live expectancy, is exclusively indicated for palliative reasons.

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Ca.Mammario

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Tecnologia	Artigianato

Qualcosa è Cambiato