

Progetto CANOA
**CARCINOMA
MAMMARIO:**

QUALI NOVITÀ PER IL 2014?

"Saper leggere" uno studio clinico per migliorare la pratica clinica

Coordinatori scientifici:

Stefania Gori

Giovanni L. Pappagallo

PROGRAMMA

Ospedaletto di Pescantina (VR) 21-22 marzo 2014

Park Hotel Villa Quaranta

***1- QUESITO GRADE:
nelle pazienti con carcinoma
mammario metastatico, la
chirurgia del tumore primitivo
aumenta la sopravvivenza?***

Dott.ssa ELENA FIORIO
AOUI Oncologia d.O.

Valutazione delle evidenze:
studi prospettici randomizzati

**SURGICAL REMOVAL OF PRIMARY TUMOR AND
AXILLARY LYMPH NODES IN WOMEN WITH
METASTATIC BREAST CANCER AT FIRST
PRESENTATION:
A RANDOMIZED CONTROLLED TRIAL**

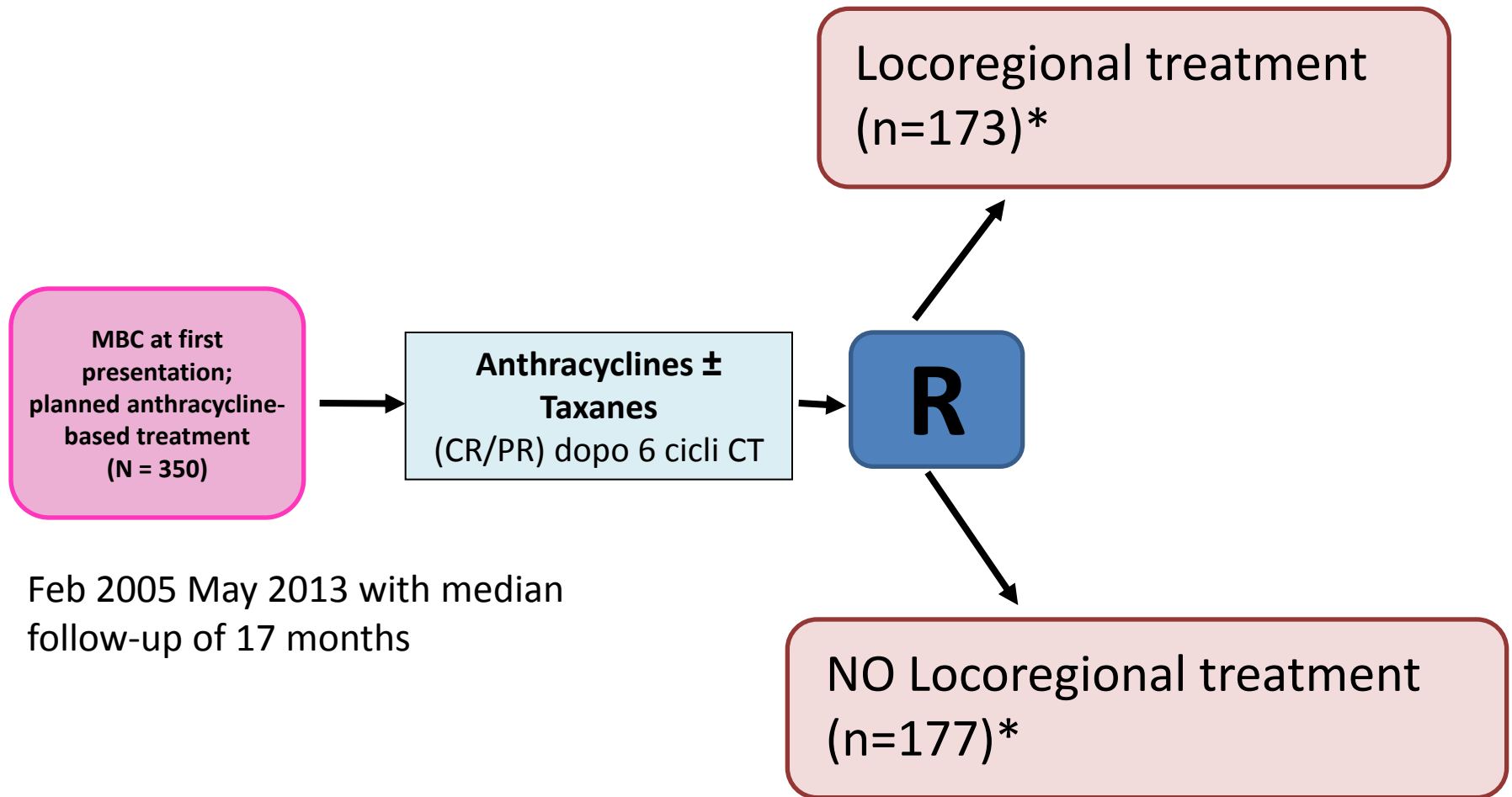
POSTER S2-02

Presenter: Rajendra Badwe, M.D. SABC 2013

AIM OF THE STUDY

To assess the effect of removal of primary tumour on overall survival in women presenting with metastatic breast cancer

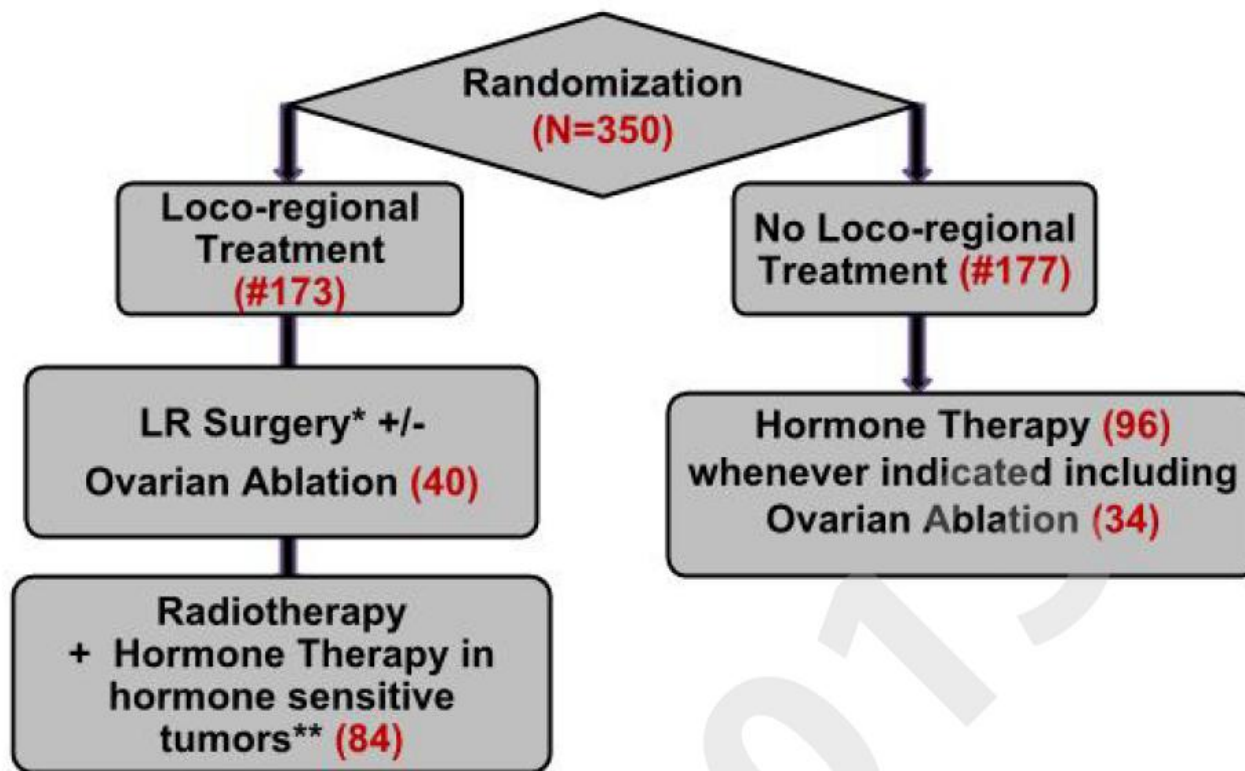
TRIAL SCHEMA



Feb 2005 May 2013 with median
follow-up of 17 months

*Breast-conserving therapy or modified radical mastectomy plus axillary lymph node dissection followed by radiation therapy (standard adjuvant guidelines).

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

STRATIFICATION

	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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POSTER S2-02

Presenter: Rajendra Badwe, M.D. SABC 2013

DEVIATION IN SURGICAL TREATMENT

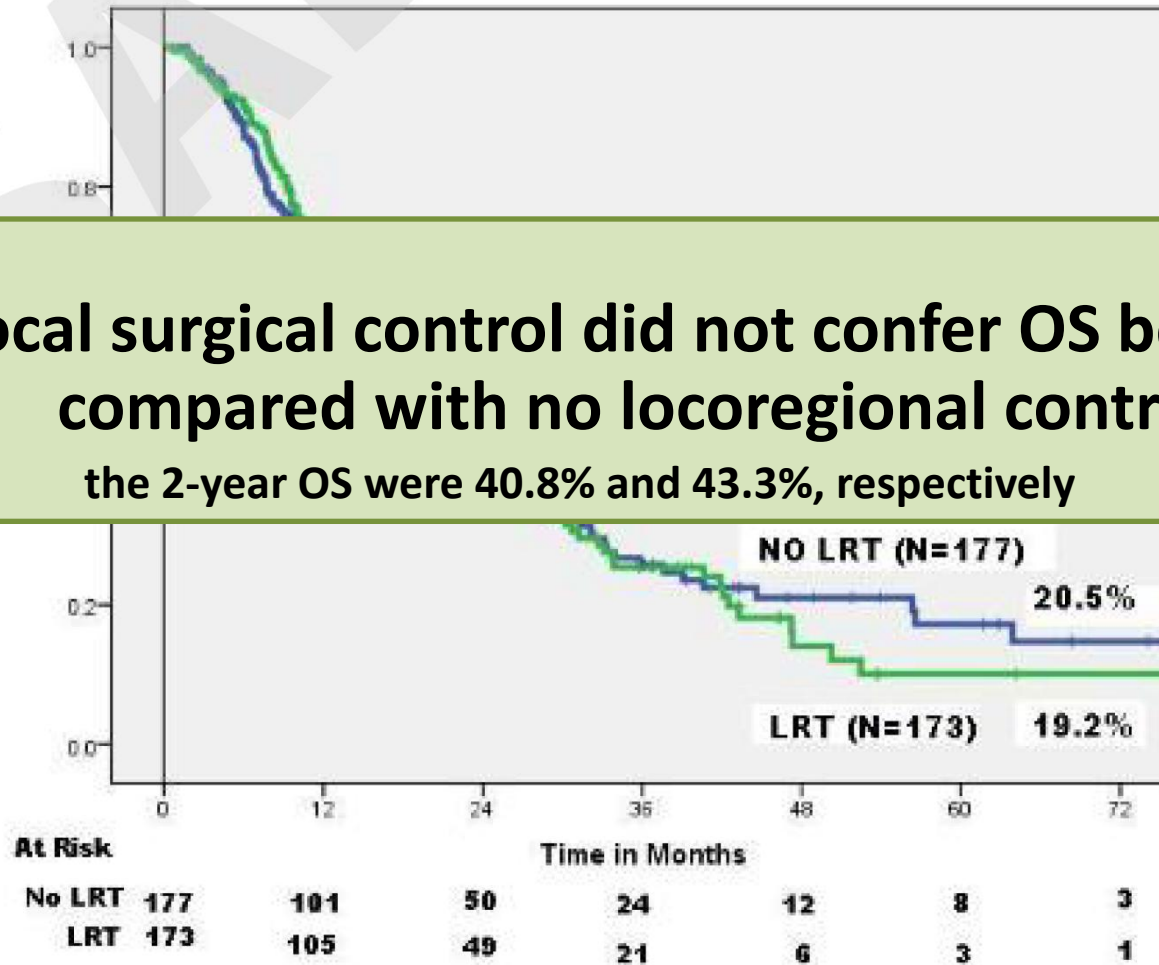
	NO LRT (177)	LRT (173)	TOTAL
Protocol Violations	3 (1.7%)	9 (5.2%)	12
Palliative Mastectomy (per protocol)	18 (10.2%)	1 (0.6%)	19

POSTER S2-02

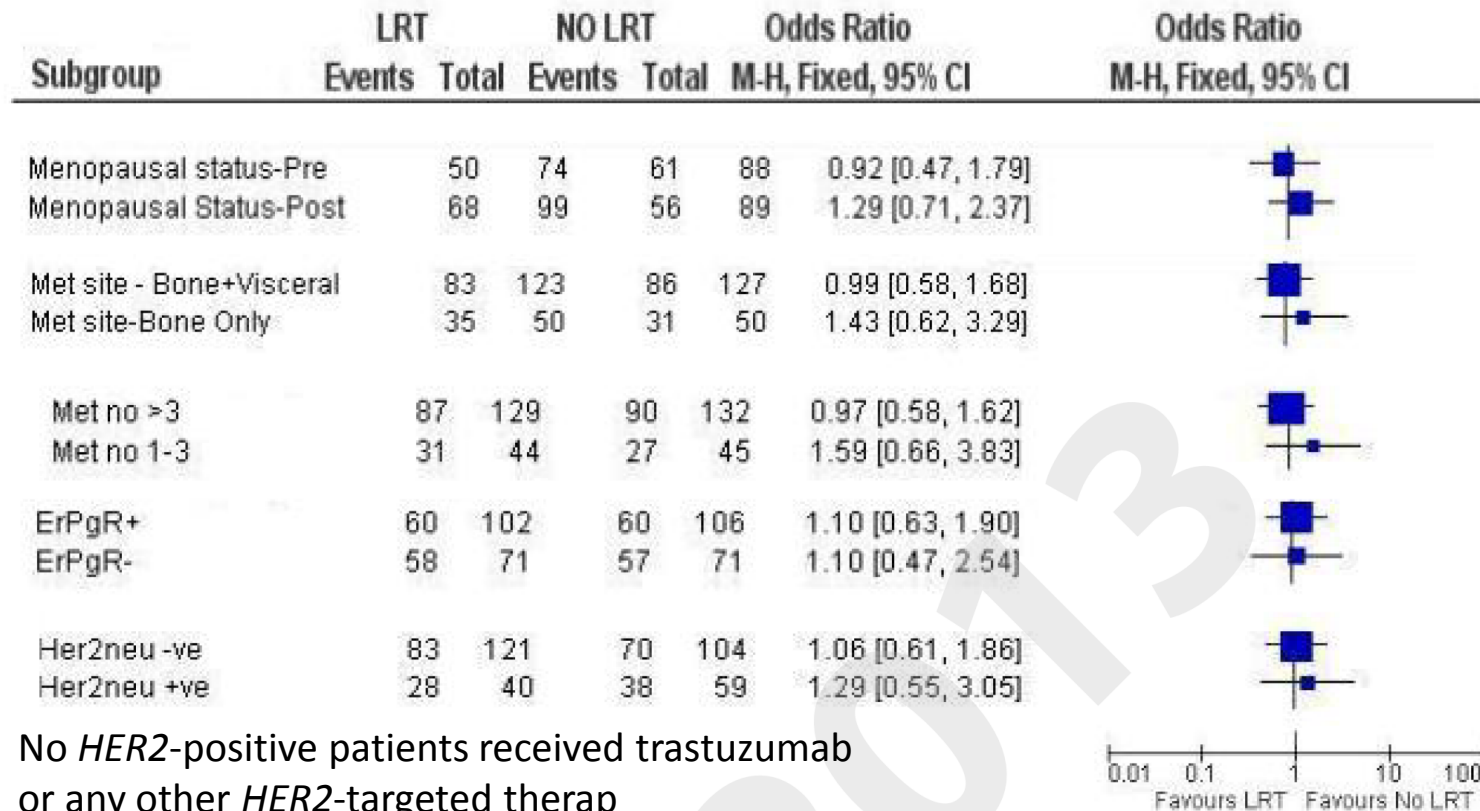
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OVERALL SURVIVAL

Local surgical control did not confer OS benefit compared with no locoregional control
the 2-year OS were 40.8% and 43.3%, respectively



SUBGROUP ANALYSIS



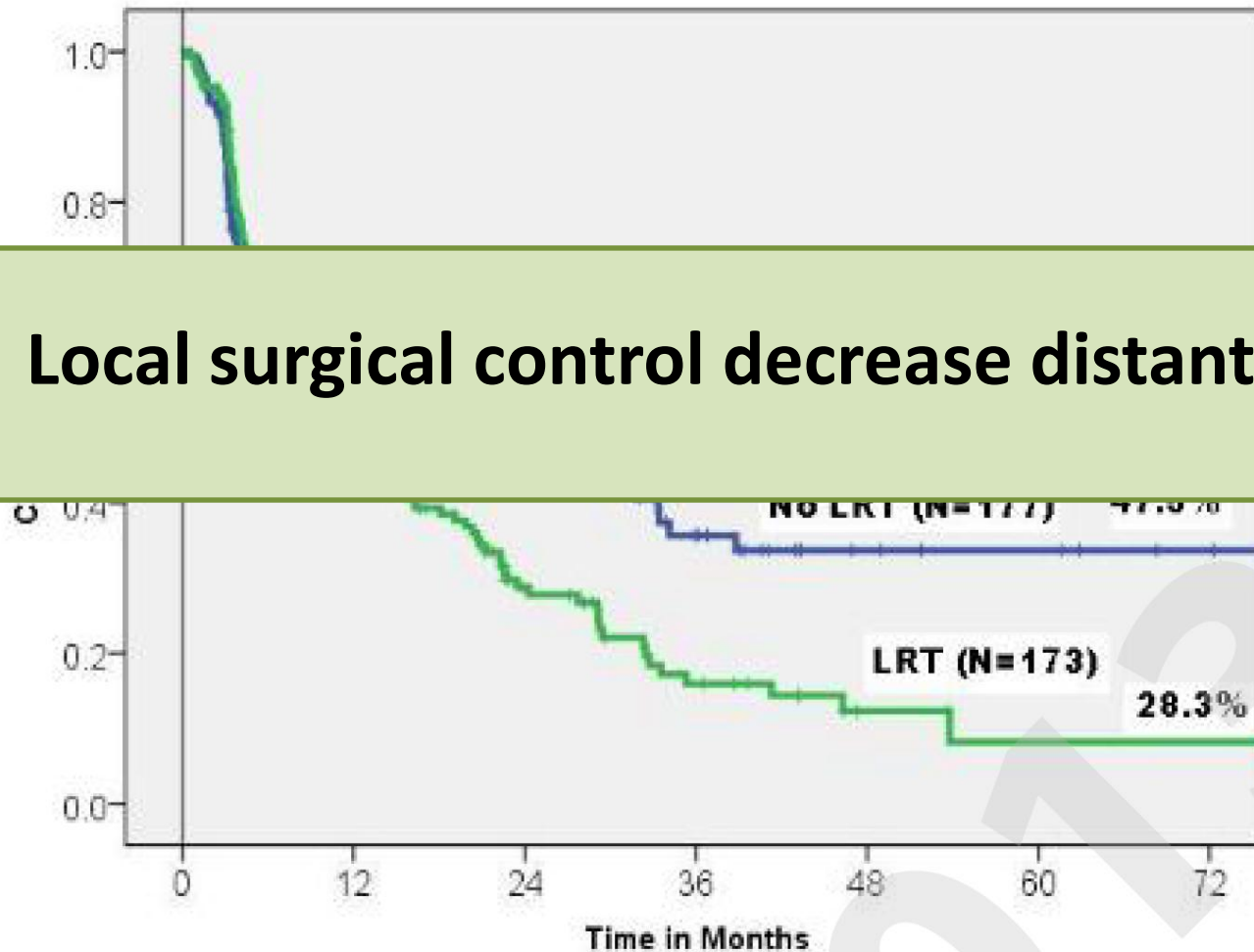
In a Cox regression model there was no significant difference in OS between LRT and No-LRT arms (HR=1.00, 95%CI=0.76-1.33, p=0.98)

POSTER S2-02

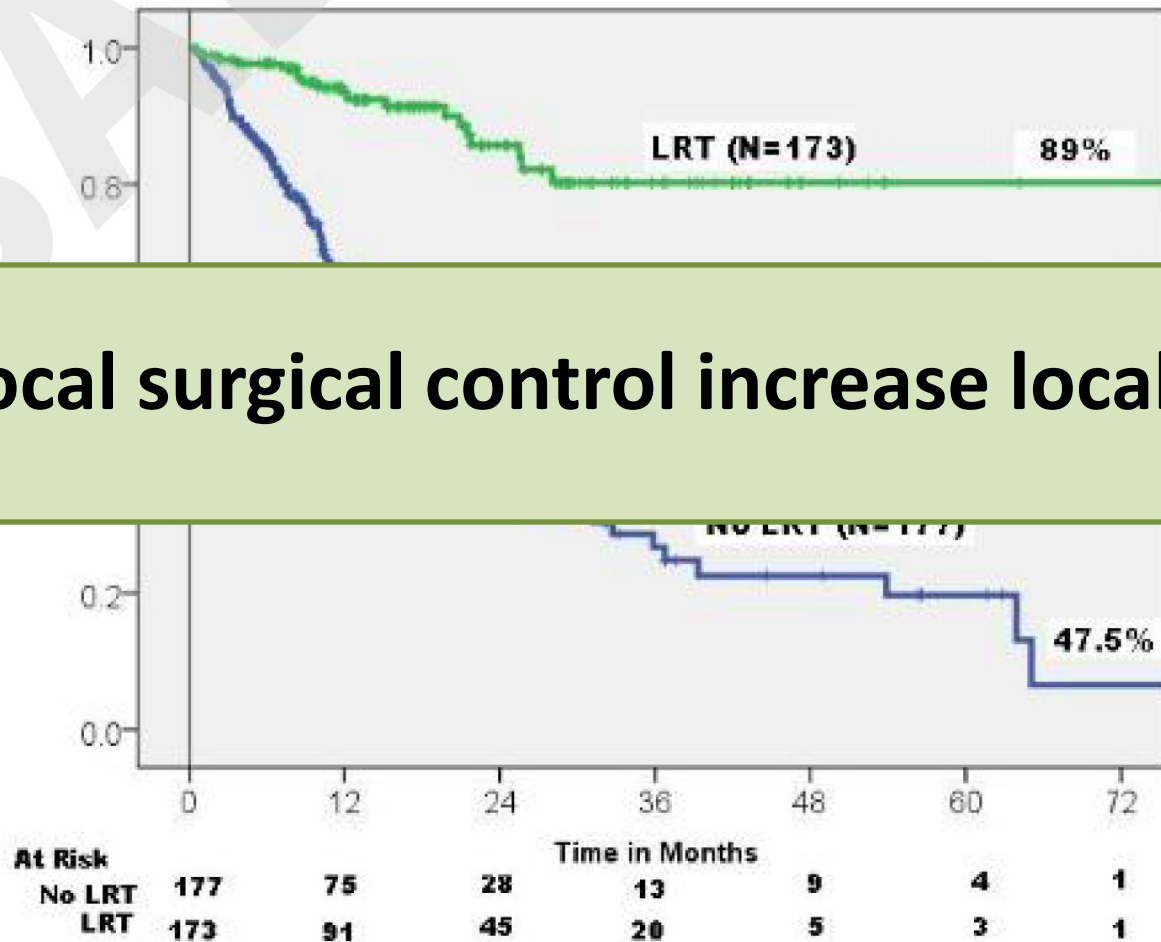
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DISTANT PFS

Local surgical control decrease distant PFS



LOCAL PFS



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CONCLUSIONS

Loco-regional treatment of the primary tumor and axillary nodes has no impact on OS in patients diagnosed with MBC at initial presentation, who have responded to frontline chemotherapy

Loco-regional treatment of the primary tumor shows a decrease of **distant PFS**

“I’m sure a lot of oncologists who believe in conventional wisdom and don’t provide loco-regional treatment will feel a lot more comfortable looking at these results,” said Badwe. “As for those who have changed practice based on the retrospective study history, they would have to rethink.”

tumour conferred a growth advantage on distant metastasis

POSTER [S2-03] 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)

Soran A, Ozmen V, Ozbas S, Karanlik H, Muslumanoglu M, Igci A, Canturk Z, Utkan Z, Ozaslan C, Evrensel T, Uras C, Aksaz E, Soyder A, Ugurlu U, Col C, Cabioglu N, Bozkurt B, Dagoglu T, Uzunkoy A, Dulger M, Koksak N, Cengiz O, Gulluoglu B, Unal B, Atalay C, Yildirim E, Erdem E, Salimoglu S, Sezer A, Koyuncu A, Gurleyik G, Alagol H, Ulufi N, Berberoglu U, Kennard E, Kelsey S, Lembersky B. Turkish Federation of Societies for Breast Diseases, Istanbul, Turkey

POSTER S2-03 SABC 2013

Presenter: ***Soran A*** M.D. ***Turkish Federation of Societies for Breast Diseases, Istanbul, Turkey***

AIM OF THE STUDY

Introduction: Previous reports of carefully selected patients presenting with stage IV breast cancer (BC) suggest that surgery on the primary tumor may result in improved survival, but this remains unproven. **The MF07-01 trial is a phase III randomized** controlled trial of BC women with distant metastases at presentation who receive loco-regional (LR) treatment for intact primary tumor compared with those who do not receive such treatment

Aim: The primary objective of the trial is to compare overall survival (OS) in women treated with or without initial LR resection prior to systemic therapy for de novo stage IV BC.

TRIAL SCHEMA

From 2008 to 2012

**MBC at first
presentation
(N = 278)**



Locoregional treatment
(n=140)* and systemic therapy[£]

* mastectomy or breast conserving surgery with level I-II axillary clearance in clinically or sentinel lymph node positive patients. Radiation therapy to whole breast was required following breast conserving surgery

NO Locoregional treatment
(n=138) but systemic therapy[£]

The mean follow up time
was 21.1+14.5 months.

[£] systemic therapy of either endocrine treatment or chemotherapy
(plus trastuzumab for HER2 +) was given to all patients

<u>Baseline Characteristics</u>	<u>Initial Surgery (n:140)</u>	<u>Systemic Tx (n:138)</u>	<u>P</u>
Age (mean years \pm SD)	51.8 \pm 12.9	51.5 \pm 13.5	ns
BMI (Kg/m ²)	27.6 \pm 5.1	28.0 \pm 5.5	ns
Mean Follow Up (Months)	21 \pm 14.6	20.9 \pm 14.5	ns
Median follow-up(min-max)	18 (1-55)	17(1-54)	ns
TUMOR SIZE	% (n)	%(n)	ns
T1	8.6 (12)	8.0 (11)	
T2	52.1 (73)	42.8 (59)	
T3	22.1 (31)	21.7 (30)	
T4	17.1 (24)	27.5 (38)	
HISTOLOGY GRADE			ns
Grade I	4.3 (6)	9.5 (10)	
Grade II	40.0 (56)	32.4 (34)	
Grade III	55.7 (78)	58.1 (61)	
TUMOR TYPE			ns
Invasive ductal	79.3(111)	84 (116)	
Invasive lobular	10.7 (15)	8.7(12)	
ER/PR (+)	86.4(121)	72.3 (99)	ns
Her 2 (+)	30.7(43)	30.4(42)	ns
Triple (-)	7.1(10)	17.4(24)	ns

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OVERALL SURVIVAL



Median Follow-up 18 months

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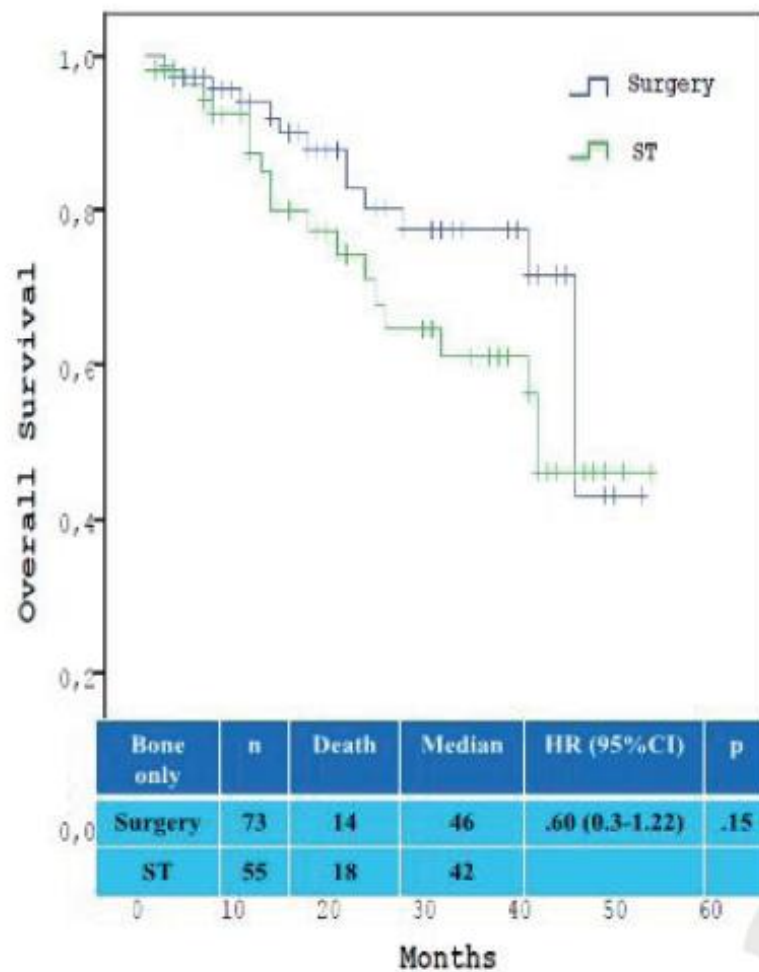
Presenter: **Soran A** M.D. *Turkish Federation of Societies for Breast Diseases, Istanbul, Turkey*

RESULTS

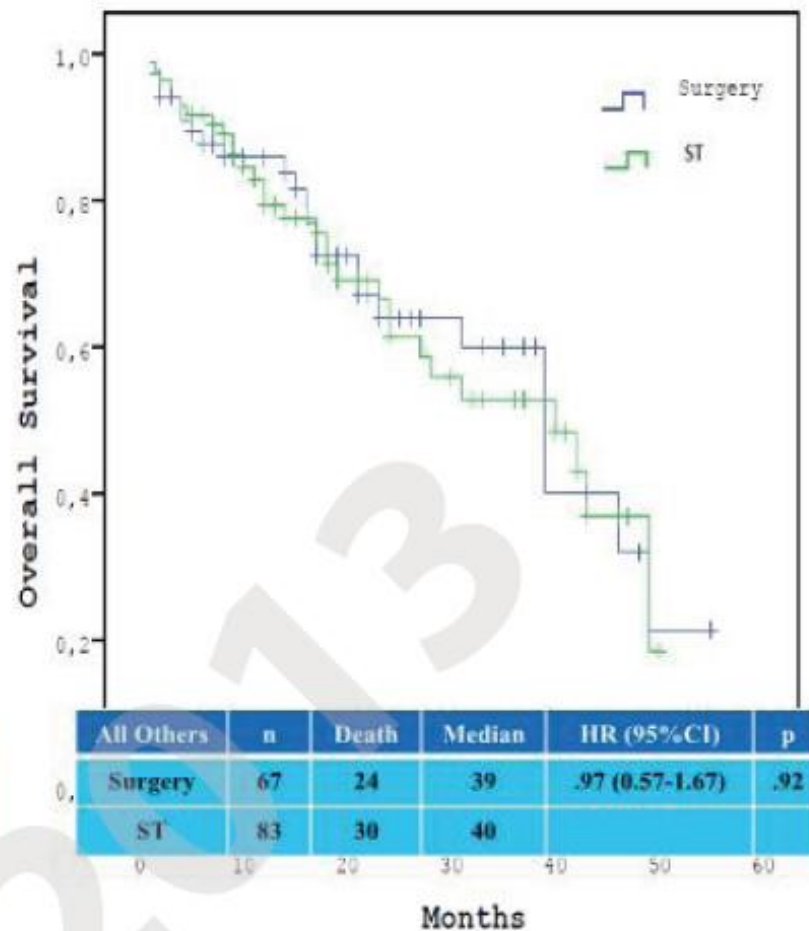
METASTATIC PATTERNS INCLUDED

- BONE ONLY 45.7%
- ORGAN EXCEPT BONE IN 28.8%
- BONE PLUS ORGAN IN 25.5%

Bone Only Met.



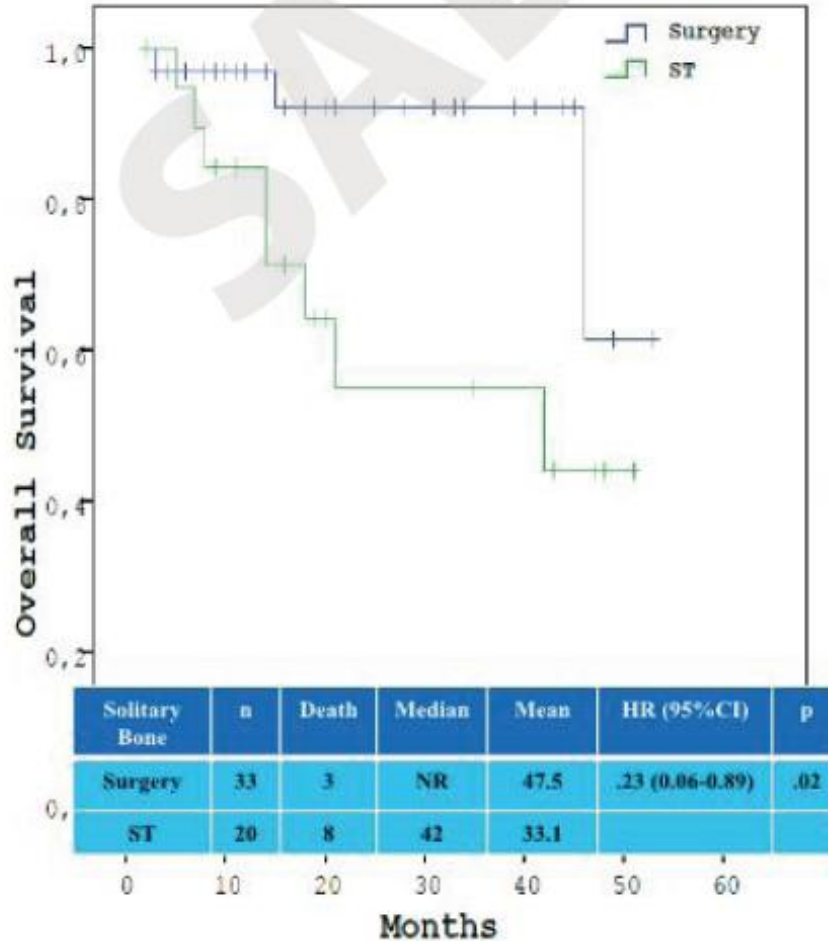
All other mets. (no Bone)



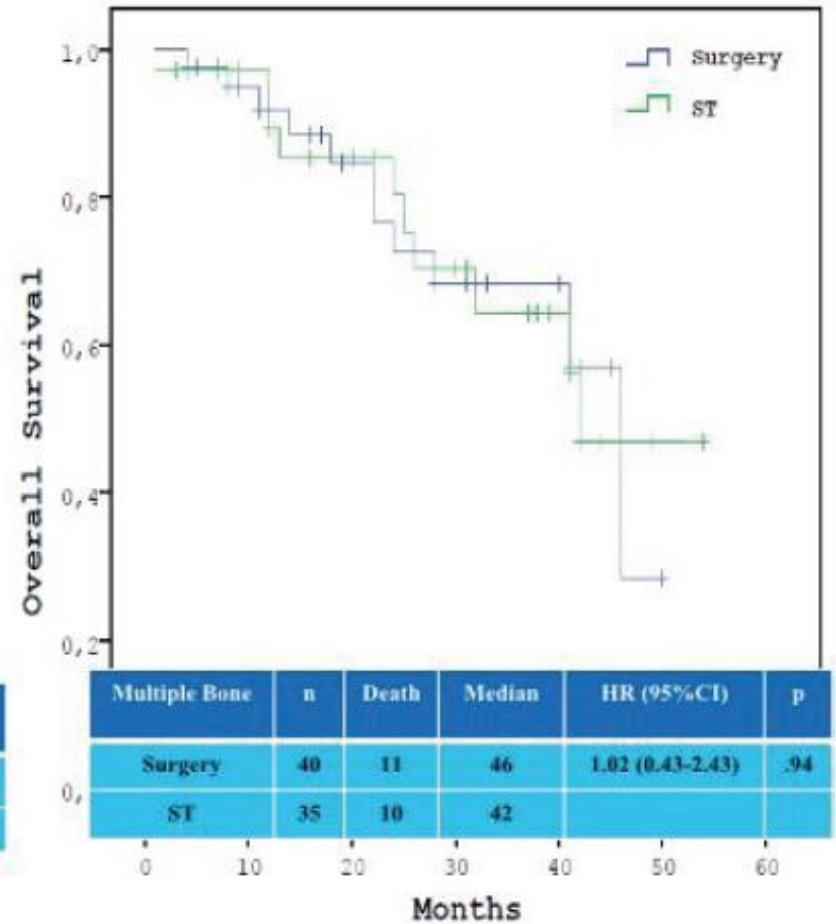
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Solitary Bone Met.



Multiple bone Met.



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Presenter: **Soran A** M.D. *Turkish Federation of Societies for Breast Diseases, Istanbul, Turkey*

RESULTS

The **mean survival was 7.1 months higher** in the surgery group compared with the no surgery group in bone only metastasis (39.1+1.8 vs 32.0+2.2; $p=0.13$).

Surgery in the group of patients who had **solitary bone only** metastasis had statistically significant survival benefit ($p=0.02$) compared with no surgery and with patients who had multiple bone metastasis either with or without surgery ($p=0.03$)

There were a total of 86 (31%) deaths

Trial's planned follow-up is 36 months

CONCLUSIONS

In early follow-up of this trial comparing surgery of the primary tumor with no surgery in stage IV BC at presentation **OS was similar but there were important subgroup differences**; in particular those with **solitary bone metastasis have a significant survival benefit and patients with bone metastasis only have a trend toward improved survival with initial surgery.**

Further follow-up will expand on these important findings.