Certificazione Europea e Carcinoma mammario metastatico

Lucio Fortunato
UOC Centro di Senologia
A.O. San Giovanni-Addolorata
Roma

13 Ottobre 2022

Senonetwork Italia Onlus

Breast Centres Certification
ITALCERT scheme in partnership with BCCERT

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

C’e’ un ruolo della chirurgia
nella malattia al IV stadio ?

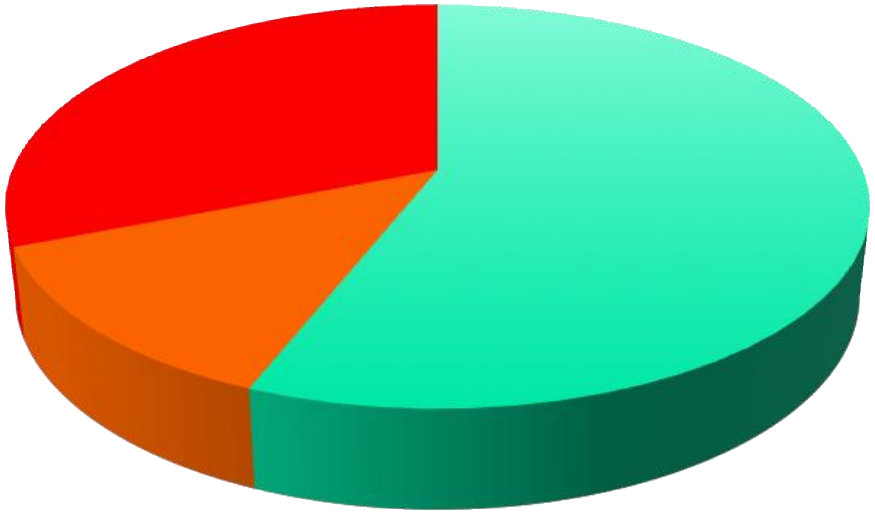
Practice Patterns - ACS National Cancer Database

ORIGINAL ARTICLE

Surgical Resection of the Primary Tumor in Women With De Novo Stage IV Breast Cancer

Contemporary Practice Patterns and Survival Analysis

Whitney O. Lane, MD, Samantha M. Thomas, MS,†‡ Rachel C. Blitzblau, MD, PhD,§*
Jennifer K. Plichta, MD, MS,† Laura H. Rosenberger, MD, MS,*†*
Oluwadamilola M. Fayanju, MD, MA, MPHS,† Terry Hyslop, PhD,†‡*
E. Shelley Hwang, MD, MPH,† and Rachel A. Greenup, MD, MPH*†*



N= 24.015
2003-2012

Terapia sistemica

- Quadrantectomia
- Mastectomia

Lane W: Ann Surg 2019: 269: 537-544

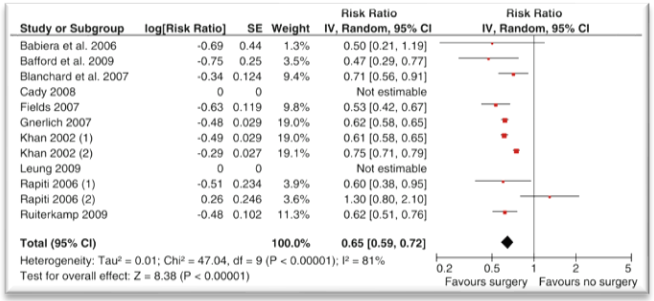
Meta-analisi studi retrospettivi

Breast Cancer Res Treat (2010) 120:9–16
DOI 10.1007/s10549-009-0670-0

REVIEW

Impact of breast surgery on survival in patients with distant metastases at initial presentation: a systematic review of the literature

Jetske Ruiterkamp · Adri C. Voogd · Koop Bosscha · Vivianne C. G. Tjan-Heijnen · Miranda F. Ernst



Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Random, 95% CI
Babiera et al. 2006	-0.69	0.44	1.3%	0.50 [0.21, 1.19]
Bafford et al. 2009	-0.75	0.25	3.5%	0.47 [0.29, 0.77]
Blanchard et al. 2007	-0.34	0.124	9.4%	0.71 [0.56, 0.91]
Cady 2008	0	0		Not estimable
Fields 2007	-0.63	0.119	9.8%	0.53 [0.42, 0.67]
Gnerlich 2007	-0.48	0.029	19.0%	0.62 [0.58, 0.65]
Khan 2002 (1)	-0.49	0.029	19.0%	0.61 [0.58, 0.65]
Khan 2002 (2)	-0.29	0.027	19.1%	0.75 [0.71, 0.79]
Leung 2009	0	0		Not estimable
Rapiti 2006 (1)	-0.51	0.234	3.9%	0.60 [0.38, 0.95]
Rapiti 2006 (2)	0.26	0.246	3.6%	1.30 [0.80, 2.10]
Ruiterkamp 2009	-0.48	0.102	11.3%	0.62 [0.51, 0.76]
Total (95% CI)			**100.0%**	**0.65 [0.59, 0.72]**

Heterogeneity: Tau² = 0.01; Chi² = 47.04, df = 9 (P < 0.00001); I² = 81%
Test for overall effect: Z = 8.38 (P < 0.00001)

10 studi
28.739 paz

Med Oncol (2012) 29:3282–3290
DOI 10.1007/s12032-012-0310-0

REVIEW ARTICLE

Surgery of primary tumors in stage IV breast cancer: an updated meta-analysis of published studies with meta-regression

Fausto Petrelli · Sandro Barni

Received: 10 July 2012 / Accepted: 14 July 2012 / Published online: 28 July 2012

Abstract Systemic therapy is the mainstream treatment of stage IV breast cancer. Surgical excision of the primary breast cancer tumor in the presence of synchronous metastatic disease is debated, but a shared indication is not proposed by current guidelines. The purpose of this analysis is to aggregate the published survival data of surgery of an intact primary tumor in stage IV disease. The authors searched PubMed for publications reporting data about the survival benefit of surgery of the primary tumor in patients with metastatic breast cancer. Hazard ratios for survival when reported after multivariate analysis (with 95 % confidence intervals) were obtained from publications and pooled in a meta-analysis. A meta-regression weighted for the extent of disease, ER/HER2 status, age, visceral or bone disease, rate of radiotherapy, and systemic therapies offered was performed. A total of 15 publications were included in this meta-analysis. Surgery of the primary tumor appeared to be an independent factor for an improved survival in the multivariate analyses from the individual studies, with an HR of 0.69 ($p < 0.00001$). According to meta-regression, the survival benefit was independent of age, extent, site of the metastatic disease, and HER2 status, but was directly proportional to the rate of patients exposed to systemic therapies and radiotherapy and inversely correlated with the ER+ status of the population included. Surgery of the primary tumor in stage IV breast cancer seems to offer a survival benefit in metastatic patients, in particular when it is offered in a multimodality treatment program.

Keywords Surgery · Primary tumor · Metastatic breast cancer · Survival

Metastatic breast cancer (MBC) is defined as the dissemination of tumor cells beyond the breast, chest wall, and regional lymph nodes. Treatment of MBC is not usually considered curative, but a small niche of patients, with limited and indolent sites of metastatic disease other than sensitivity to treatment, may experience very long survivals. This gain survival has been reached with better chemotherapy and targeted therapies in particular. The treatment goals in stage IV disease are prolongation of survival, control of burden of disease, reduction in cancer-related symptoms or complications, and maintenance of quality of life. These objectives are usually obtained with systemic therapies (e.g., endocrine therapy, chemotherapy, or biological agents) and in some circumstances with locoregional treatments (e.g., radiotherapy for painful bone lesions or surgery for solitary nodal, lung, or liver metastasis). There is a subset of women with MBC who have limited systemic tumor spread and a biologically indolent disease. Between 5 and 10 % of patients with stage IV disease survive five or more years, and 2–5 % become long-term survivors [1, 2]. These long-term survivors tend to be young, with an excellent performance status and limited metastatic (sometimes referred to as oligometastatic) disease. For such patients, combined modality approaches, often including surgery, appear to provide more hope for long-term progression-free survival than chemotherapy alone.

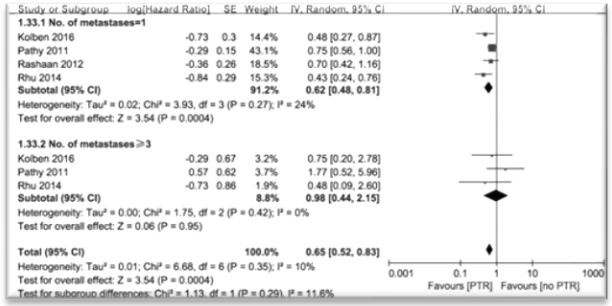
Primary breast cancer (BC) showing synchronous, distant metastases at presentation is present in a small percentage (3–4 %) in all BC patients, in which both the distant and locoregional controls of disease are endpoints

F. Petrelli (✉) · S. Barni
Medical Oncology Unit, Oncology Department, Azienda Ospedaliera Treviglio-Caravaggio, Piazzale Ospedale 1, 24047 Treviglio, BG, Italy
e-mail: faupe@libero.it

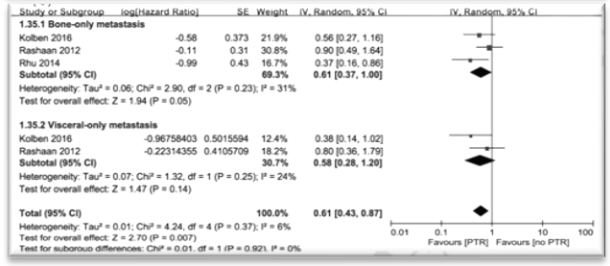
Springer

Primary Tumor Resection in Stage IV Breast Cancer: A Systematic Review and Meta-analysis

Weikai Xiao, MD, Yutian Zou, MD, Shaoquan Zheng, MD, Xiaoqian Hu, BSc, Peng Liu, MD, Xinhua Xie, MD, Ping Yu, MD, Hailin Tang, MD, PhD, Xiaoming Xie, MD, PhD



Study or Subgroup	log[Hazard Ratio]	SE	Weight	IV, Random, 95% CI
1.33.1 No. of metastases=1				
Kolben 2016	-0.73	0.3	14.4%	0.48 [0.27, 0.87]
Pathy 2011	-0.29	0.15	43.1%	0.75 [0.56, 1.00]
Rashaan 2012	-0.36	0.26	18.5%	0.70 [0.42, 1.16]
Rhu 2014	-0.84	0.29	15.3%	0.43 [0.24, 0.76]
Subtotal (95% CI)			**91.2%**	**0.62 [0.48, 0.81]**
Heterogeneity: Tau² = 0.02; Chi² = 3.93, df = 3 (P = 0.27); I² = 24%				
Test for overall effect: Z = 3.54 (P = 0.0004)				
1.33.2 No. of metastases ≥3				
Kolben 2016	-0.29	0.67	3.2%	0.75 [0.20, 2.78]
Pathy 2011	0.57	0.62	3.7%	1.77 [0.52, 5.96]
Rhu 2014	-0.73	0.86	1.9%	0.48 [0.09, 2.60]
Subtotal (95% CI)			**8.8%**	**0.98 [0.44, 2.15]**
Heterogeneity: Tau² = 0.00; Chi² = 1.75, df = 2 (P = 0.42); I² = 0%				
Test for overall effect: Z = 0.06 (P = 0.95)				
Total (95% CI)			**100.0%**	**0.65 [0.52, 0.83]**
Heterogeneity: Tau² = 0.01; Chi² = 6.68, df = 6 (P = 0.35); I² = 10%				
Test for overall effect: Z = 3.54 (P = 0.0004)				
Test for subgroup differences: Chi² = 1.13, df = 1 (P = 0.29), I² = 11.6%				



Study or Subgroup	log[Hazard Ratio]	SE	Weight	IV, Random, 95% CI
1.35.1 Bone-only metastasis				
Kolben 2016	-0.58	0.373	21.9%	0.56 [0.27, 1.16]
Rashaan 2012	-0.11	0.31	30.8%	0.90 [0.49, 1.64]
Rhu 2014	-0.99	0.43	16.7%	0.37 [0.16, 0.86]
Subtotal (95% CI)			**69.3%**	**0.61 [0.37, 1.00]**
Heterogeneity: Tau² = 0.06; Chi² = 2.90, df = 2 (P = 0.23); I² = 31%				
Test for overall effect: Z = 1.94 (P = 0.05)				
1.35.2 Visceral-only metastasis				
Kolben 2016	-0.96758403	0.5015594	12.4%	0.38 [0.14, 1.02]
Rashaan 2012	-0.22314355	0.4105709	18.2%	0.80 [0.36, 1.79]
Subtotal (95% CI)			**30.7%**	**0.58 [0.28, 1.20]**
Heterogeneity: Tau² = 0.07; Chi² = 1.32, df = 1 (P = 0.25); I² = 24%				
Test for overall effect: Z = 1.47 (P = 0.14)				
Total (95% CI)			**100.0%**	**0.61 [0.43, 0.87]**
Heterogeneity: Tau² = 0.01; Chi² = 4.24, df = 4 (P = 0.37); I² = 6%				
Test for overall effect: Z = 2.70 (P = 0.007)				
Test for subgroup differences: Chi² = 0.01, df = 1 (P = 0.92), I² = 0%				

33 studi
67.272 paz

Ruiterkamp et al: Breast Cancer Res Treat 2010; 120: 9-16

Petrelli F et al: Med Onocol 2012; 29: 3382-3290 – 15 Studi su 29.563 paz.

Xiao W et al: EJSO 2018; 44: 1504-1512

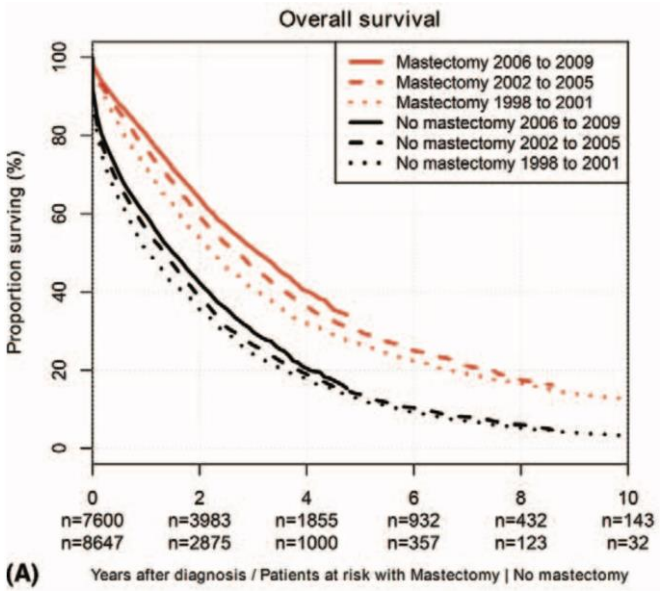
Studi Propensity Score Matched

ORIGINAL ARTICLE

Improved Survival After Primary Tumor Surgery in Metastatic Breast Cancer

A Propensity-adjusted, Population-based SEER Trend Analysis

Rene Warschkow, MD, MSc,† Ulrich Güller, MD, MHS, FEBS,‡§ Ignazio Tarantino, MD, MSc,¶ Thomas Cerny, MD,‡ Bruno M. Schmied, MD, MBA,* Beat Thuerlimann, MD,|| and Markus Joerger, MD, PhD‡*



- ✓ SEER Database
- ✓ N= 16247
- ✓ 1998-2009

Warschkow R et al: Ann Surg Oncol 2019; 26: 356-365

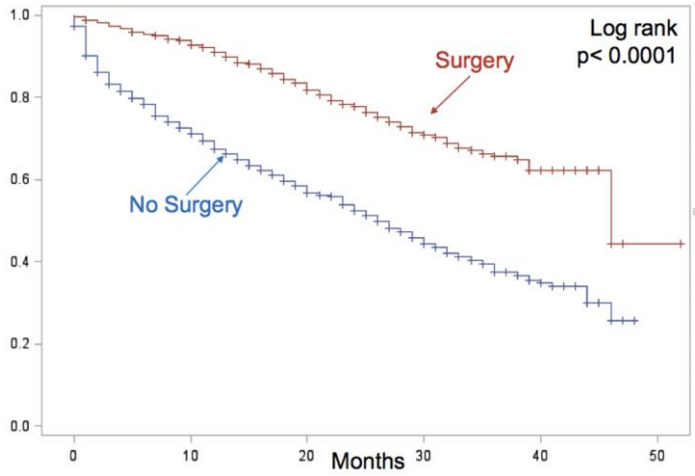
THE IMPACT OF PRIMARY TUMOR SURGERY ON SURVIVAL IN HER2 POSITIVE STAGE IV BREAST CANCER PATIENTS IN THE CURRENT ERA OF TARGETED THERAPY

Ross Mudgway BS, Carlos Chavez de Paz Villanueva MD MPH, Ann C. Lin MD, Maheswari Senthil MD, Carlos A. Garberoglio MD, Sharon S. Lum MD

LOMA LINDA UNIVERSITY School of Medicine

Commission on Cancer NCDB

AACR American Association for Cancer Research FINDING CURES TOGETHER



- ✓ NCDB (2.807.541 casi)
- ✓ 58.867 NEU +
- ✓ 2010-2012
- ✓ 3231 pazienti stadio IV

Courtesy Sharon S Lum, Loma Linda University, 2019

E quindi.. ??

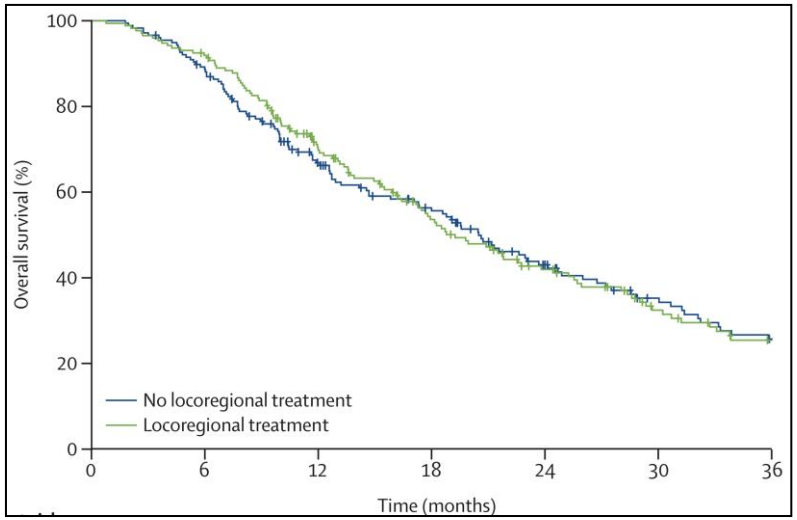
Trials Randomizzati

Country	Accrual Period	N Projected	N Accrual	Initial Therapy	Status
India (Tata Memorial)	2005-12	350	350	Systemic Therapy	Published
Turkey (MF 07-01)	2008-12	271	274	Surgery	Published
USA and Canada ECOG 2108	2011-16	880	368	Systemic Therapy	Published
Japan JCOG 1017	2011-18	500	400	Systemic Therapy	Completed
Austria (ABCSG 28) (POSYTIVE)	2010-15	254	90	Surgery	Early Stopped
Netherlands (SUBMIT)	2011-16	516	0	Surgery	Early Stopped

Tata Memorial Trial

Locoregional treatment versus no treatment of the primary tumour in metastatic breast cancer: an open-label randomised controlled trial

Rajendra Badwe, Rohini Hawaldar, Nita Nair, Rucha Kaushik, Vani Parmar, Shabina Siddique, Ashwini Budrukkar, Indraneel Mittra, Sudeep Gupta



- Randomized trial, N= 350
- Chemioterapia up-front
- randomizzate solo le pazienti "responders"
- Stratificazione per Numero e Sito delle metastasi, e recettori ormonali
- Nessun trattamento con Herceptin nelle pazienti HER2/neu +

Badwe R: Lancet Oncology 2015; 16: 1380-8

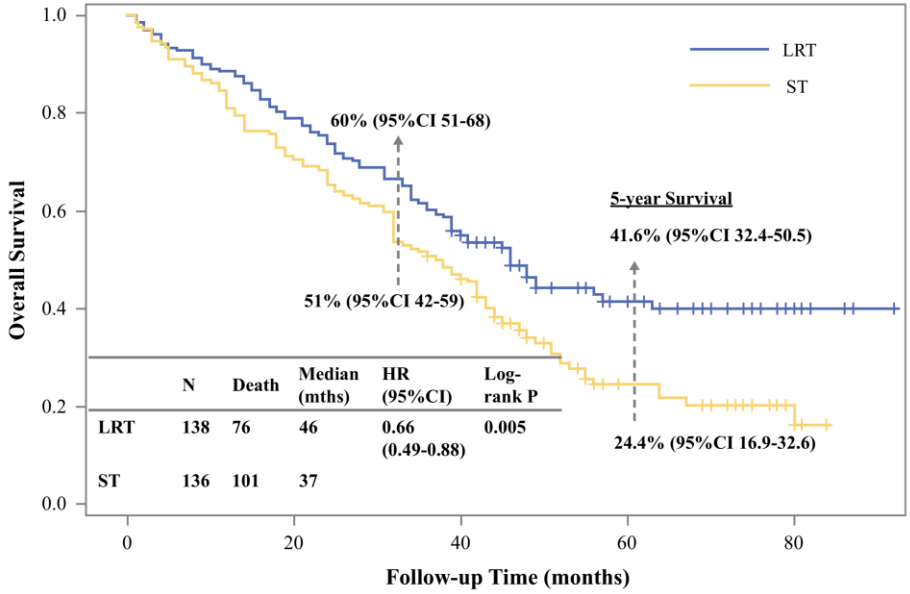
Turkish Trial MF07-01

Ann Surg Oncol
https://doi.org/10.1245/s10434-018-6494-6
Annals of SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Randomized Trial Comparing Resection of Primary Tumor with No Surgery in Stage IV Breast Cancer at Presentation: Protocol MF07-01

Atilla Soran, MD, MPH, FNCBC, FACS[1], Vahit Ozmen, MD, FACS[2], Serdar Ozbas, MD[3], Hasan Karanlik, MD[4], Mahmut Muslumanoglu, MD[5], Abdullah Igci, MD[5], Zafer Canturk, MD[6], Zafer Utkan, MD[7], Cihangir Ozaslan, MD[8], Turkkan Evrensel, MD[9], Cihan Uras, MD[10], Erol Aksaz, MD[11], Aykut Soyder, MD[12], Umit Ugurlu, MD[13],



	N	Death	Median (mths)	HR (95%CI)	Log-rank P
LRT	138	76	46	0.66 (0.49-0.88)	0.005
ST	136	101	37		

- 274 pazienti valutabili, Età media 51 anni
- No stratification
- (ER + 85% in S – vs. 72% in ST
- Mets ossee non confermate istologicamente
- Follow-up mediano 40 mesi

Soran A: Ann Surg Oncol 2018; 25: 3141-3149

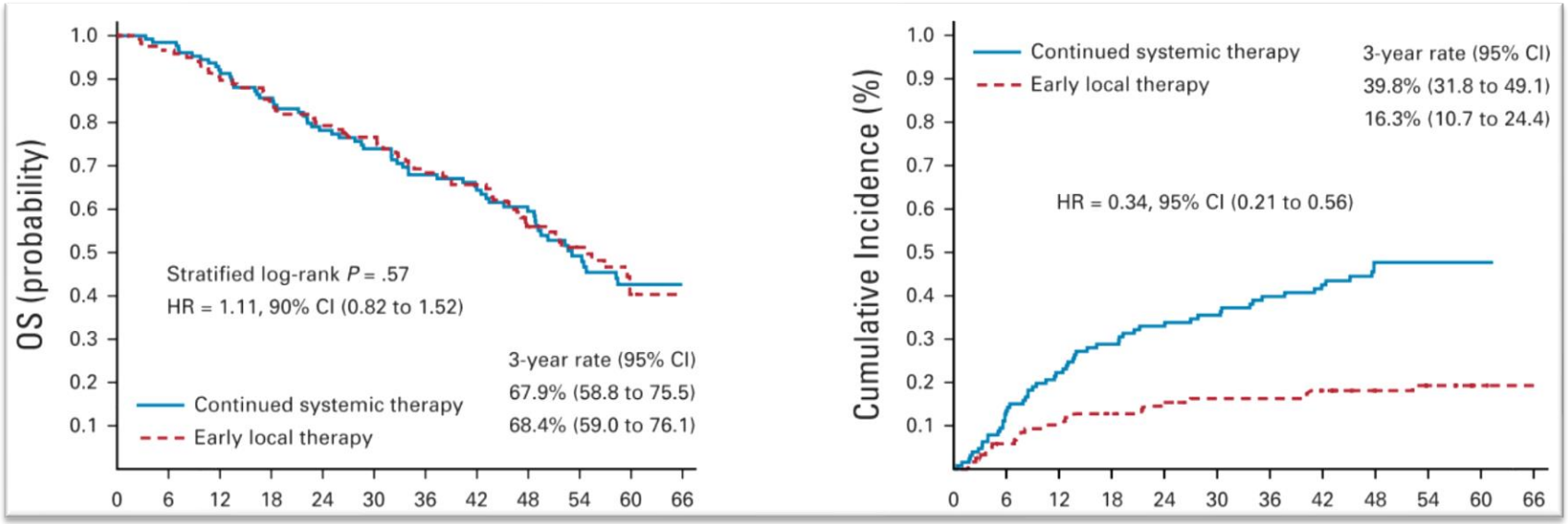
ECOG 2108

original reports

Early Local Therapy for the Primary Site in De Novo Stage IV Breast Cancer: Results of a Randomized Clinical Trial (EA2108)

Seema A. Khan, MD, MPH[1]; Fengmin Zhao, MS, MHS, PhD[2]; Lori J. Goldstein, MD[3]; David Cella, PhD[4]; Mark Basik, MD[5]; Mehra Golshan, MD, MBA[6]; Thomas B. Julian, MD[7]; Barbara A. Pockaj, MD[8]; Christine A. Lee, MD[9]; Wajeeha Razaq, MD[10]; Joseph A. Sparano, MD[11]; Gildy V. Babiera, MD[12]; Irene A. Dy, MD[13]; Sarika Jain, MD[1]; Paula Silverman, MD[14]; Carla S. Fisher, MD[15]; Amye J. Tevaarwerk, MD[16]; Lynne I. Wagner, PhD[17]; and George W. Sledge, MD[18]

N= 391 pazienti registrate
2/3 randomizzate
Free margins of resection
Adjuvant RT
ACOSOG Z11 criteria for SLN
Primary endpoint: OS
Secondary: QOL (FACT)
Start 2011-Closed 2019



CONCLUSION Early locoregional therapy for the primary site did not improve survival in patients presenting with metastatic breast cancer. Although it was associated with improved locoregional control, this had no overall impact on quality of life.

Sheema Khan, et al: JCO, March 2020 - 2022

Metanalisi degli Studi prospettici

Ann Surg Oncol (2021) 28:5059–5070
https://doi.org/10.1245/s10434-021-09650-3

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

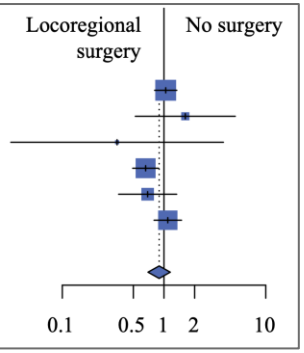
Clinical Evidence for Locoregional Surgery of the Primary Tumor in Patients with De Novo Stage IV Breast Cancer

Yunfang Yu, MD[1], Huangming Hong, MD[1], Ying Wang, MD[1], Tuping Fu, MD[2], Yongjian Chen, MD[3], Jianli Zhao, MD[1], Peixian Chen, MD[4], Ruizhao Cai, MD[2], Yujie Tan, MD[1], Zifan He, MD[1], Wei Ren, MD[1], Lihuan Zhou, MD[2], Junhao Huang, MD[2], Jun Tang, MD[2], Guolin Ye, MD[4], and Herui Yao, MD[1]

Overall Survival

Study	Year	Locoregional surgery	No surgery	HR	95%CI	Weight
TATA	2015	173	177	1.04	(0.81; 1.34)	30.1%
TBCRC-013	2016	39	47	1.62	(0.52; 5.02)	4.5%
Abo-Touk	2016	27	30	0.35	(0.03; 3.84)	1.1%
MF07-01	2018	138	136	0.66	(0.49; 0.88)	27.3%
ABCSG-28	2018	45	45	0.69	(0.36; 1.33)	11.0%
ECOG-ACRIN-2108	2020	129	129	1.09	(0.80; 1.49)	26.0%
				0.90	(0.70; 1.15)	100.0%

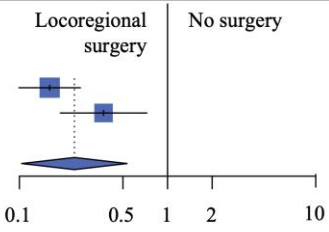
Heterogeneity: $I^2 = 46\%$, $\tau^2 = 0.0386$, $P = 0.10$
Test for overall effect: $z = -0.85$ ($P = 0.40$)



Loco-regional Progression-free Survival

Study	Year	Locoregional surgery	No surgery	HR	95%CI	Weight
TATA	2015	173	177	0.16	(0.10; 0.26)	54.2%
ECOG-ACRIN-2108	2020	124	122	0.37	(0.19; 0.73)	45.8%
				0.23	(0.10; 0.53)	100.0%

Heterogeneity: $I^2 = 75\%$, $\tau^2 = 0.2627$, $P = 0.05$
Test for overall effect: $z = -3.47$ ($P < 0.01$)



- ✓ Metanalisi di studi prospettici
- ✓ Propensity Score Matching
- ✓ 1110 pazienti
- ✓ 6 Studi

Yu Y, et al: Ann Surg Oncol 2021; 28: 5059-5070

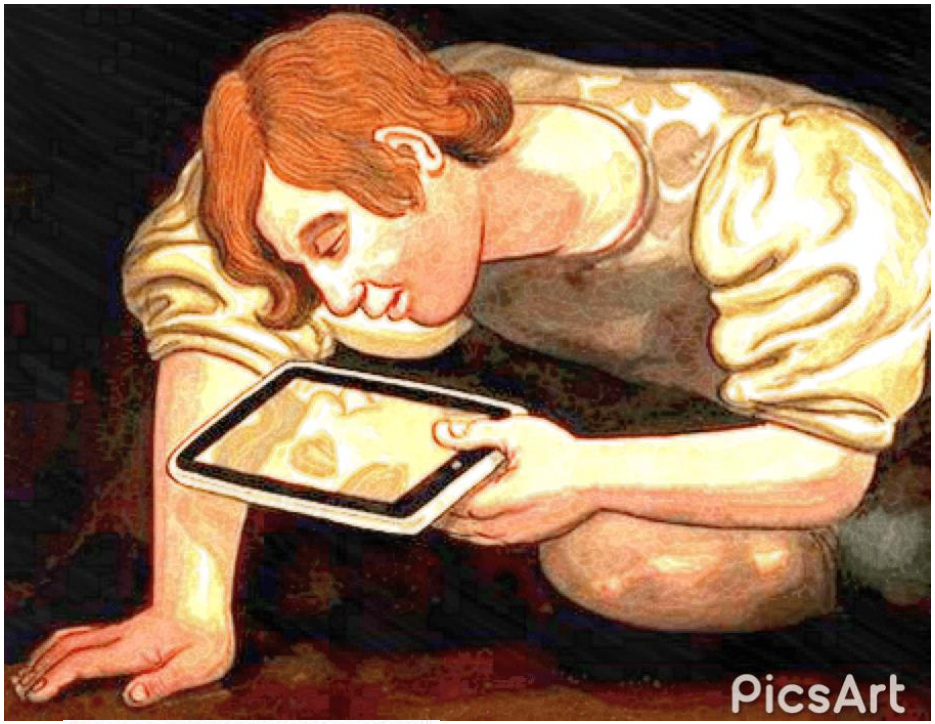
Conclusioni

- Non è dimostrato un beneficio consistente della chirurgia in studi randomizzati
- Studi retrospettivi sono inquinati da bias
- La chirurgia, quando ipotizzata, non dovrebbe avere come obiettivo l'aumento della sopravvivenza
- Pazienti con tumori triplo negativi o metastasi viscerali non dovrebbero essere considerate per chirurgia a meno di necessità palliative
- E' possible considerare la chirurgia come trattamento "non-standard" in alcuni casi selezionati ?
- Practice Patterns ?

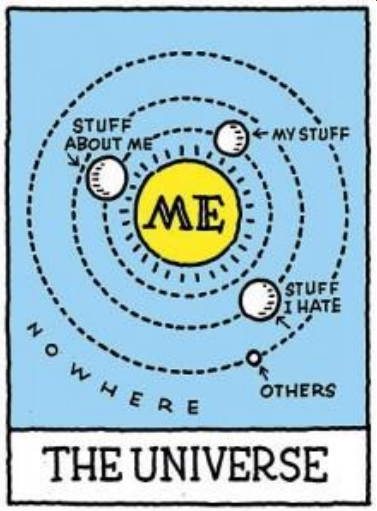
Certificazione Europea

Perché abbiamo bisogno di una Certificazione?

Auto-referenzialità

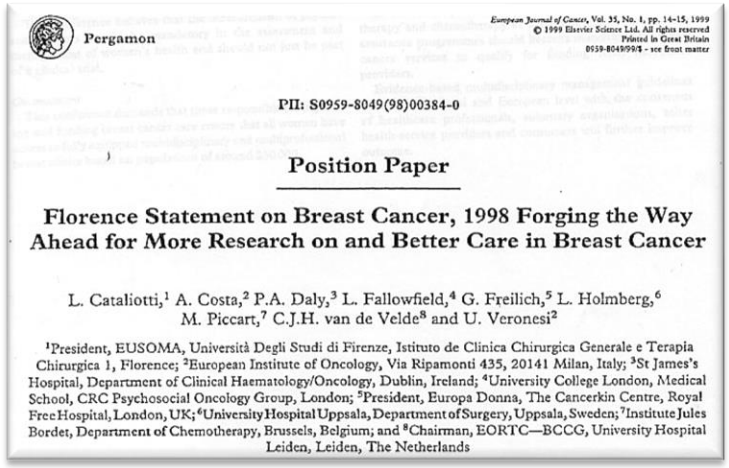


CI STIAMO
PARLANDO ADDOSSO?



Certificazione Europea

- Firenze, 1998: EBCC 1, Florence Statement
- Risoluzioni del Parlamento Europeo nel 2003-2006
- EUSOMA recommendations
  - Minimum 150 cases/year
  - Multidisciplinary approach, MDM
  - Mandatory Core Team
- Ente Certificatorio: BCCERT/Italcert
- Quality indicators
- Data warehouse



Pergamon

European Journal of Cancer, Vol. 35, No. 1, pp. 14–15, 1999
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Printed in Great Britain
0959-8049/99/$ - see front matter

PII: S0959-8049(98)00384-0

Position Paper

Florence Statement on Breast Cancer, 1998 Forging the Way Ahead for More Research on and Better Care in Breast Cancer

L. Cataliotti,[1] A. Costa,[2] P.A. Daly,[3] L. Fallowfield,[4] G. Freilich,[5] L. Holmberg,[6] M. Piccart,[7] C.J.H. van de Velde[8] and U. Veronesi[2]

[1]President, EUSOMA, Università Degli Studi di Firenze, Istituto de Clinica Chirurgica Generale e Terapia Chirurgica 1, Florence; [2]European Institute of Oncology, Via Ripamonti 435, 20141 Milan, Italy; [3]St James's Hospital, Department of Clinical Haematology/Oncology, Dublin, Ireland; [4]University College London, Medical School, CRC Psychosocial Oncology Group, London; [5]President, Europa Donna, The Cancerkin Centre, Royal Free Hospital, London, UK; [6]University Hospital Uppsala, Department of Surgery, Uppsala, Sweden; [7]Institute Jules Bordet, Department of Chemotherapy, Brussels, Belgium; and [8]Chairman, EORTC—BCCG, University Hospital Leiden, Leiden, The Netherlands

EUROPEAN PARLIAMENT 2009 - 2014

14.12.2009 0071/2009

WRITTEN DECLARATION

pursuant to Rule 123 of the Rules of Procedure

on the fight against breast cancer in the European Union

Elizabeth Lynne, Michail Tremopoulos, Lívia Járóka, Lidia Joanna Geringer de Oedenberg

Lapse date: 25.3.2010

In Italia

2014 – Rete dei Centri di Senologia Conferenza Stato-Regioni

Presidenza del Consiglio dei Ministri

CONFERENZA PERMANENTE PER I RAPPORTI
TRA LO STATO, LE REGIONI E LE PROVINCIE AUTONOME
DI TRENTO E DI BOLZANO

Intesa, ai sensi dell'articolo 8, comma 6 della legge 5 giugno 2003, n. 131, sul documento recante "Linee di indirizzo sulle modalità organizzative ed assistenziali della rete dei Centri di Senologia".

Rep. Atti n. 185/CSR del 18 dicembre 2014

LA CONFERENZA PERMANENTE PER I RAPPORTI TRA LO STATO, LE REGIONI E LE PROVINCE AUTONOME DI TRENTO E BOLZANO

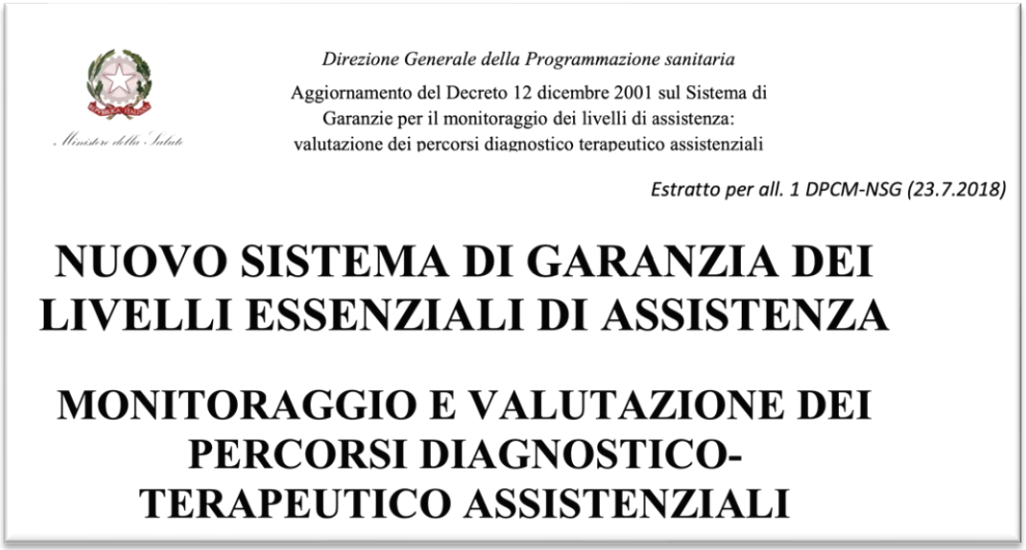
Nell' odierna seduta del 18 dicembre 2014:

VISTO l'articolo 8, comma 6 della legge 5 giugno 2003, n. 131, che prevede la possibilità per il Governo di promuovere, in sede di Conferenza Stato-Regioni o di Conferenza Unificata, la stipula di intese dirette a favorire l'armonizzazione delle rispettive legislazioni o il raggiungimento di posizioni unitarie o il conseguimento di obiettivi comuni;

VISTO l'art. 168 del trattato di Lisbona dell' Unione Europea, che prevede che debbano essere assicurati elevati livelli di protezione della salute nella definizione ed implementazione di tutte le politiche ed attività dell'Unione;

VISTO il decreto legislativo n.502 del 30 dicembre 1992 e successive modificazioni ed integrazioni, che indirizza le azioni del Servizio Sanitario Nazionale verso il rispetto del principio di appropriatezza e l' individuazione di percorsi diagnostici terapeutici e linee guida;

2018 – Centri di Senologia - LEA



Ministero della Salute

Direzione Generale della Programmazione sanitaria

Aggiornamento del Decreto 12 dicembre 2001 sul Sistema di Garanzie per il monitoraggio dei livelli di assistenza: valutazione dei percorsi diagnostico terapeutico assistenziali

Estratto per all. 1 DPCM-NSG (23.7.2018)

NUOVO SISTEMA DI GARANZIA DEI LIVELLI ESSENZIALI DI ASSISTENZA

MONITORAGGIO E VALUTAZIONE DEI PERCORSI DIAGNOSTICO-TERAPEUTICO ASSISTENZIALI

Requisiti per la certificazione

The Breast 51 (2020) 65–84

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Original article

The requirements of a specialist breast centre

Laura Biganzoli [a, *, 1], Fatima Cardoso [b, 1], Marc Beishon [c], David Cameron [d], Luigi Cataliotti [e], Charlotte E. Coles [f], Roberto C. Delgado Bolton [g], Maria Die Trill [h], Sema Erdem [i], Maria Fjell [j], Romain Geiss [k], Mathijs Goossens [l], Christiane Kuhl [m], Lorenza Marotti [n], Peter Naredi [o], Simon Oberst [p], Jean Palussière [q], Antonio Ponti [r], Marco Rosselli Del Turco [s], Isabel T. Rubio [t], Anna Sapino [u], Elzbieta Senkus-Konefka [v], Marko Skelin [w], Berta Sousa [x], Tiina Saarto [y], Alberto Costa [c], Philip Poortmans [z]

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ABSTRACT

This article is an update of the requirements of a specialist breast centre, produced by EUSOMA and endorsed by ECCO as part of Essential Requirements for Quality Cancer Care (ERQCC) programme, and ESMO.

To meet aspirations for comprehensive cancer control, healthcare organisations must consider the requirements in this article, paying particular attention to multidisciplinarity and patient-centred pathways from diagnosis, to treatment, to survivorship.

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[1] Laura Biganzoli and Fatima Cardoso are both first authors and declare equal contribution to this article.

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Position Paper

Quality indicators in breast cancer care: An update from the EUSOMA working group

Laura Biganzoli [a,*], Lorenza Marotti [b], Christopher D. Hart [a,c], Luigi Cataliotti [d], Bruno Cutuli [e], Thorsten Kühn [f], Robert E. Mansel [g], Antonio Ponti [h], Philip Poortmans [i], Peter Regitnig [l], Jos A. van der Hage [m], Yvonne Wengström [n], Marco Rosselli Del Turco [o]

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KEYWORDS
Quality indicators;
Breast cancer care

Abstract In 2010, EUSOMA published a position paper, describing a set of benchmark quality indicators (QIs) that could be adopted by breast centres to allow standardised auditing and quality assurance and to establish an agreed minimum standard of care. Towards the end of 2014, EUSOMA decided to update the paper on QIs to consider and incorporate new scientific knowledge in the field. Several new QIs have been included to address the need for improved follow-up care of patients following primary treatments. With regard to the management of elderly patients, considering the complexity, the expert group decided that, for some specific quality indicators, if centres fail to meet the minimum standard, older patients will be excluded from analysis, provided that reasons for non-adherence to the QI are specified in the clinical chart and are identified at the review of the clinical records. In this way, high standards are promoted, but centres are able to identify and account for the effect of non-

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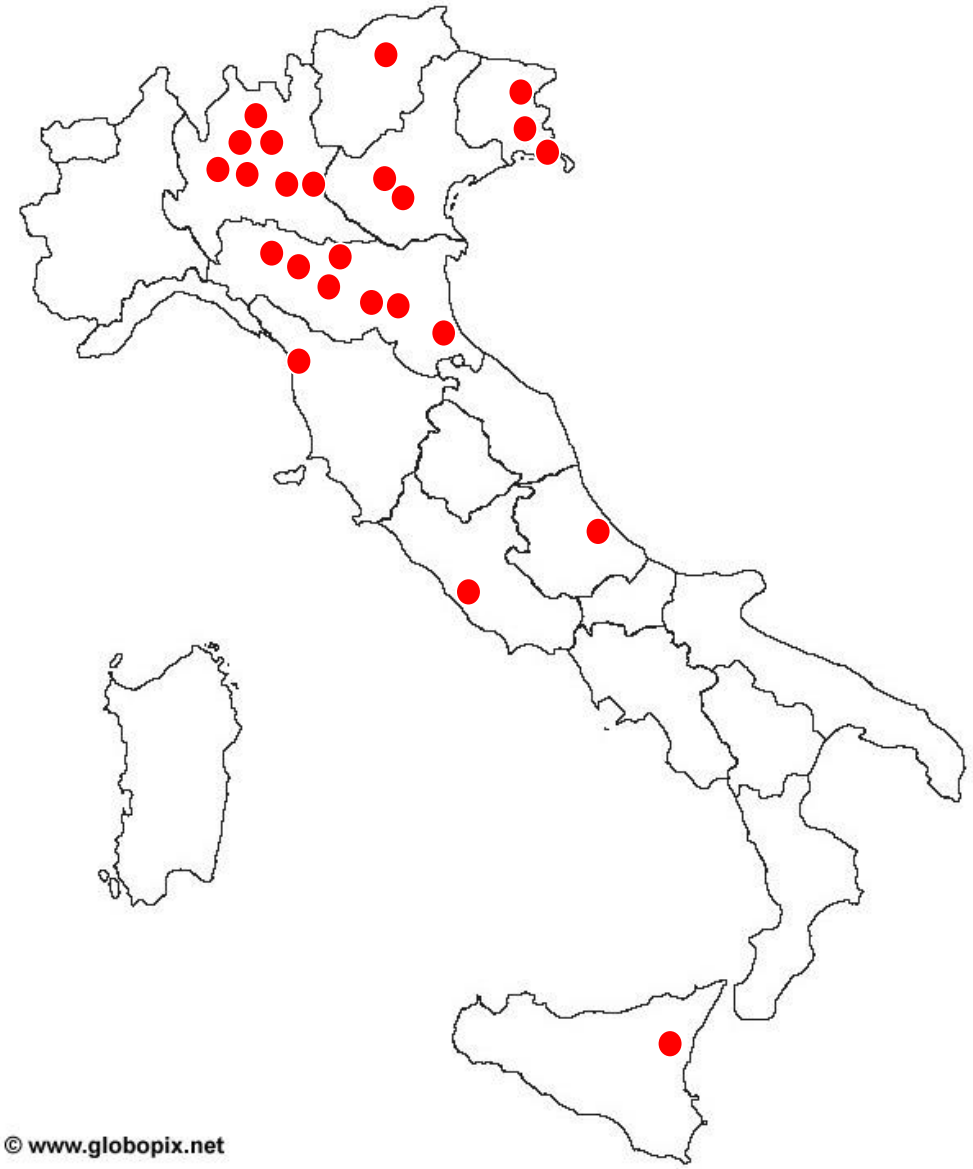
Biganzoli L et al: EJC 2017; 86: 59-81

Centri Certificati in Italia



Breast Centres Certification

ITALCERT scheme in partnership with BCCERT

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Breast Centres Cert

European Breast Centres Certification

ITALCERT Srl is a Certification Body accredited by ACCREDIA for management systems, products and services, inspection activities and notified body for conformity assessment according to CE Type-approval mark

Bccert is a no profit Association aiming at promoting and diffusing an high quality standard of care in breast cancer and it is partner of Italcert for what concerns Certification scheme according to Eusoma guidelines

ACCREDIA

L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023 A
SGA N° 020D
PRS N° 079C
PRD N° 122B
SCR N° 041F
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Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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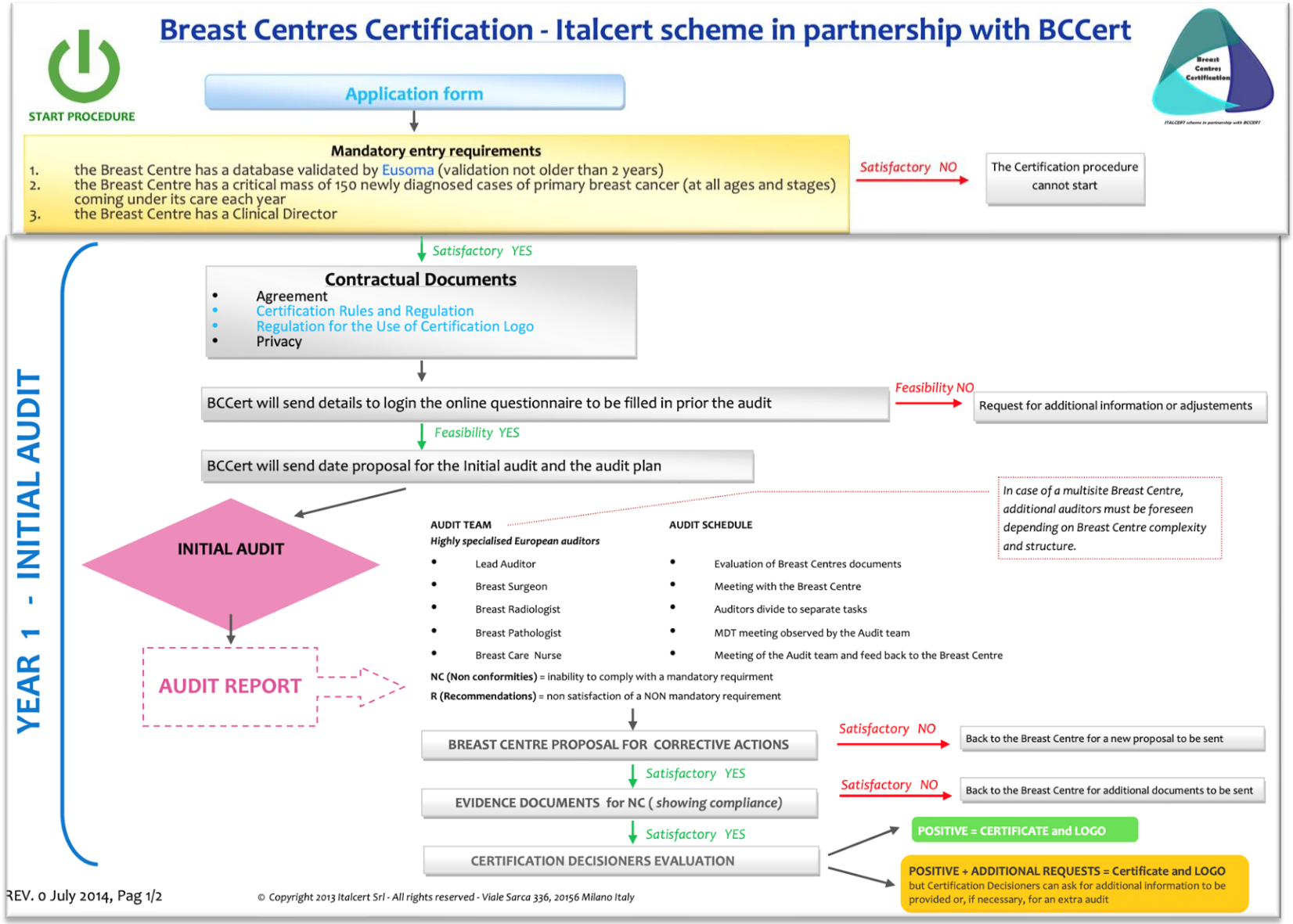

Indicatori di Qualità

EUSOMA
European Society of Breast Cancer Specialists

Eusoma Quality Indicators for Breast Centre Certification

based on "Quality indicators in breast cancer care: An update from the EUSOMA working group" EJC 86 (2017): 59-81

Breast Centres Certification Procedure

According to the Eusoma guidelines "The requirements of a specialist breast centre"

	Indicator	Recommended/ Mandatory	Minimum Standard	Target
1	Proportion of women with breast cancer (invasive or in situ) who had a pre-operative histologically or cytologically confirmed malignant diagnosis (B5 or C5)	M	85%	90%
2	Proportion of invasive cancer cases for which the following prognostic/predictive parameters have been recorded: histological type (according to WHO Classification of Tumours of the Breast), grading (according to WHO and EU Guidelines: Elston and Ellis modified Bloom and Richardson-Grading system Elston, CW et al. 1991), ER, PgR*, HER-2/neu, Proliferation index (Ki67)* *this marker is recommended but not mandatory, and does not need to be included in the calculation for compliance with the QI For patients receiving primary systemic treatment (PST), characterization on core biopsy prior to therapy is mandatory. For patients receiving primary surgery, characterization may be performed on the surgical specimen only. In addition to the above parameters, the following parameters must be recorded after surgery: Pathological stage (pT and pN, or ypT and ypN in case of PST), Size in mm for the invasive component, Peritumoral vascular invasion (L,V), Distance to nearest radial margin	M	95%	98%

Indicatori di Qualità

EUSOMA
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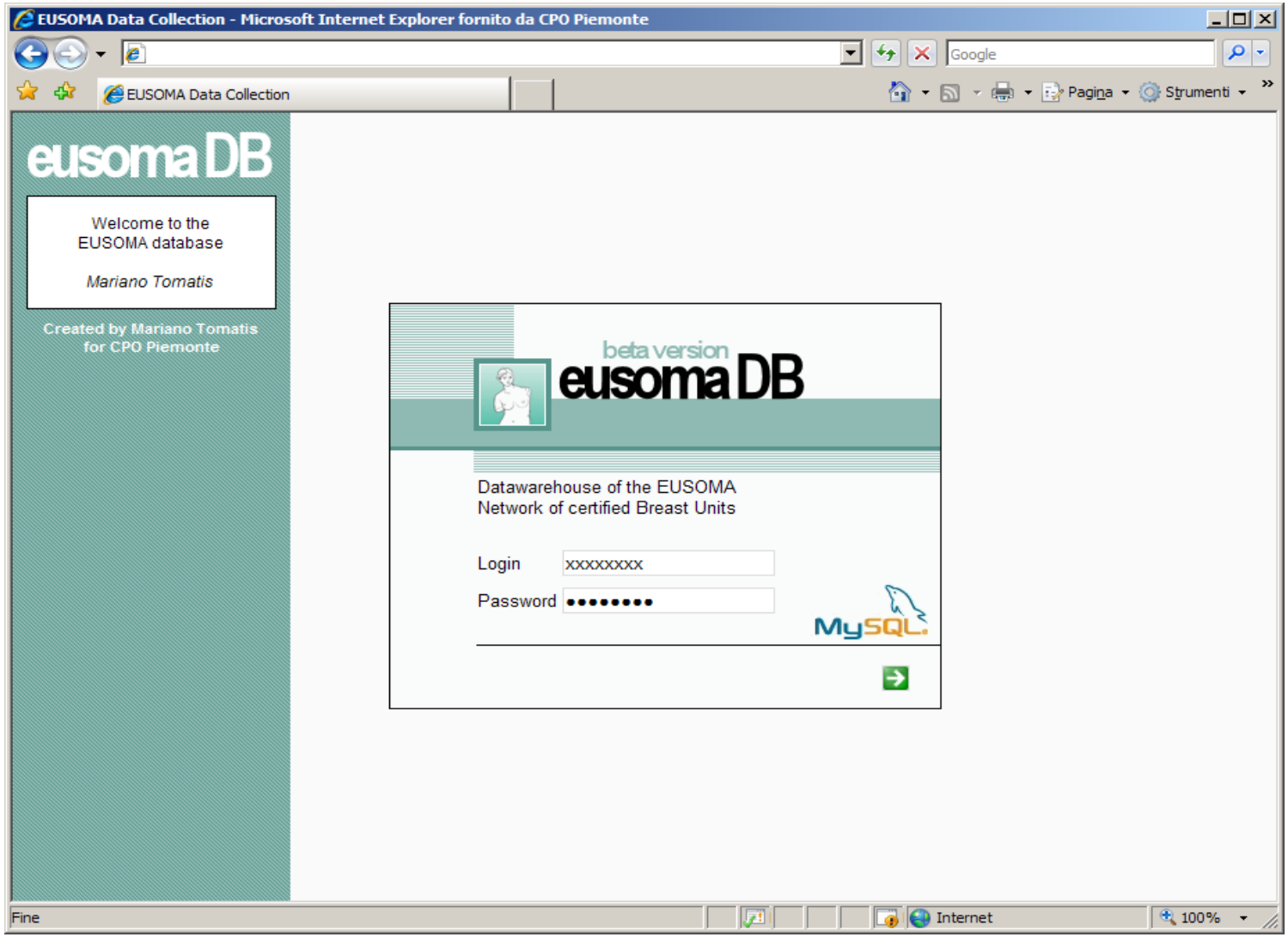
		Recommended/ Mandatory	Minimum Standard	Target
3	Proportion of non-invasive cancer cases for which the following prognostic/predictive parameters have been recorded: Grading (according to WHO Classification of Tumours of the Breast), dominant histologic pattern, size in mm (best pathology or radiology estimate if 2 stage pathology), distance to nearest radial margin, ER.	M	95%	98%
4	Proportion of patients with invasive breast cancer (M0) who received post-operative radiation therapy (RT) after surgical resection of the primary tumor and appropriate axillary staging/surgery in the framework of BCT	M	90 %	95 %
5	Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment.	M	70%	85%
6	Proportion of patients with non-invasive breast cancer not greater than 2cm who underwent BCT	M	80%	90%
7	Proportion of patients with DCIS only who do not undergo axillary clearance	M	97%	99%

Indicatori di Qualità

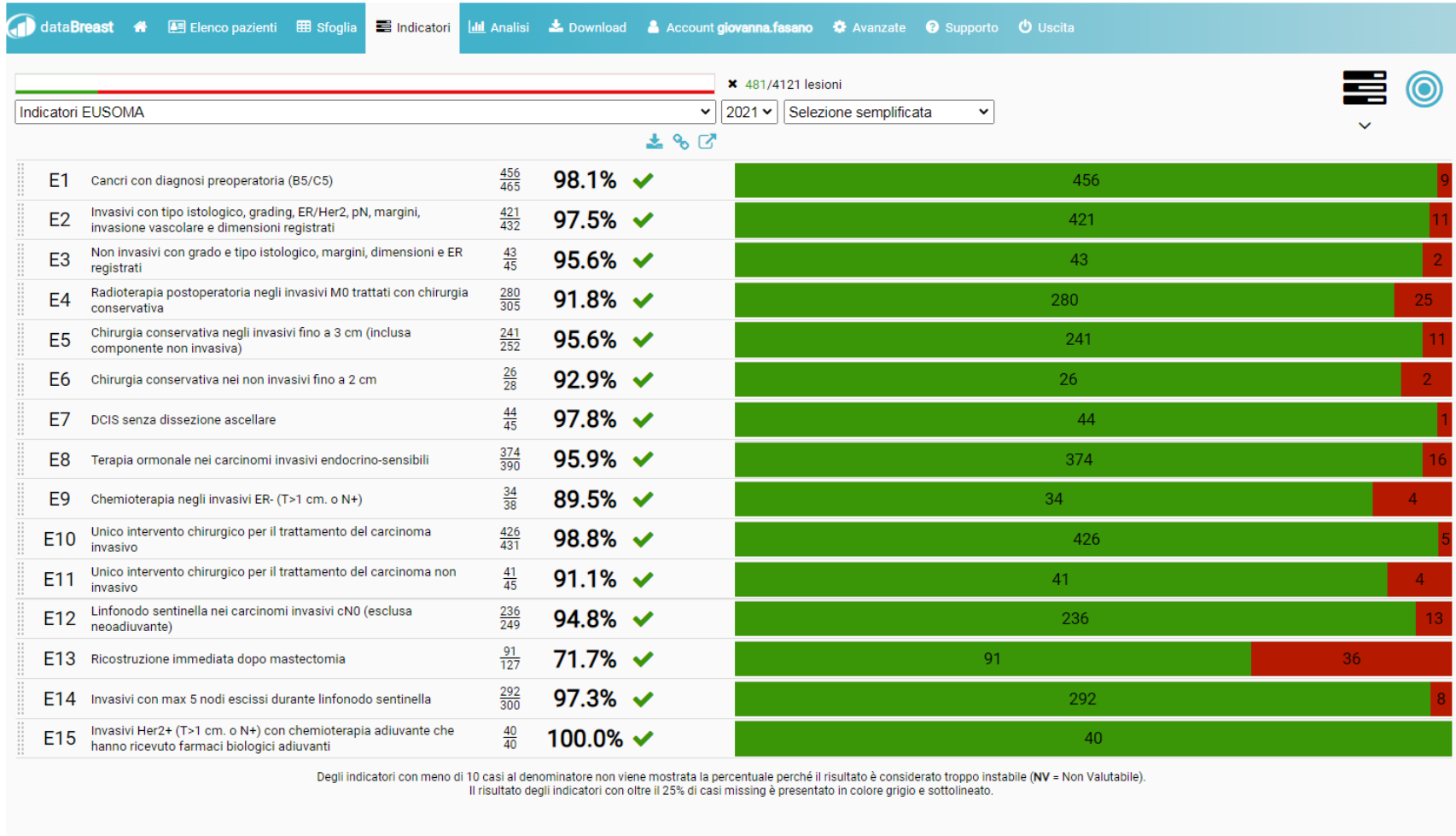
		Recommended/ Mandatory	Minimum Standard	Target
8	Proportion of patients with endocrine sensitive invasive cancer who received endocrine therapy	M	85%	90%
9	Proportion of patients with ER– (T > 1 cm or Node+) invasive carcinoma who received adjuvant chemotherapy	M	85%	95%
10	Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumor (excluding reconstruction)	M	80%	90%
11	Proportion of patients (DCIS only) who received just one operation (excluding reconstruction)	M	70%	90%
12	Proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy (excluding patients who received PST)	M	90%	95%
13	Proportion of patients receiving immediate reconstruction at the same time of mastectomy	R	40%	NA
14	Proportion of patients with invasive cancer who underwent sentinel lymph-node biopsy with no more than 5 nodes excised	R	90%	95%
15	Proportion of patients with HER2 positive (IHC 3+ or in situ hybridisation positive FISH +) invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab	M	85%	95%
16	Proportion of treated patients for which the breast centre collects data on life status and recurrence rate (for at least 5 years)	R	80%	90%
17*	Ratio of benign to malignant diagnoses based on definitive pathology report (surgery only, non-operative biopsies excluded) –	M	1:4	1:5

Data base


EUSOMA Data Collection - Microsoft Internet Explorer fornito da CPO Piemonte
EUSOMA Data Collection
eusoma DB
Welcome to the EUSOMA database
Mariano Tomatis
Created by Mariano Tomatis for CPO Piemonte
beta version
eusoma DB
Datawarehouse of the EUSOMA Network of certified Breast Units
Login
xxxxxxxx
Password
MySQL
Fine
Internet
100%

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

2021 EUSOMA Indicators



E1	Cancri con diagnosi preoperatoria (B5/C5)	456/465	98.1%	456	9
E2	Invasivi con tipo istologico, grading, ER/Her2, pN, margini, invasione vascolare e dimensioni registrati	421/432	97.5%	421	11
E3	Non invasivi con grado e tipo istologico, margini, dimensioni e ER registrati	43/45	95.6%	43	2
E4	Radioterapia postoperatoria negli invasivi M0 trattati con chirurgia conservativa	280/305	91.8%	280	25
E5	Chirurgia conservativa negli invasivi fino a 3 cm (inclusa componente non invasiva)	241/252	95.6%	241	11
E6	Chirurgia conservativa nei non invasivi fino a 2 cm	26/28	92.9%	26	2
E7	DCIS senza dissezione ascellare	44/45	97.8%	44	1
E8	Terapia ormonale nei carcinomi invasivi endocrino-sensibili	374/390	95.9%	374	16
E9	Chemioterapia negli invasivi ER- (T>1 cm. o N+)	34/38	89.5%	34	4
E10	Unico intervento chirurgico per il trattamento del carcinoma invasivo	426/431	98.8%	426	5
E11	Unico intervento chirurgico per il trattamento del carcinoma non invasivo	41/45	91.1%	41	4
E12	Linfonodo sentinella nei carcinomi invasivi cN0 (esclusa neoadiuvante)	236/249	94.8%	236	13
E13	Ricostruzione immediata dopo mastectomia	91/127	71.7%	91	36
E14	Invasivi con max 5 nodi escissi durante linfonodo sentinella	292/300	97.3%	292	8
E15	Invasivi Her2+ (T>1 cm. o N+) con chemioterapia adiuvante che hanno ricevuto farmaci biologici adiuvanti	40/40	100.0%	40	

Degli indicatori con meno di 10 casi al denominatore non viene mostrata la percentuale perché il risultato è considerato troppo instabile (**NV** = Non Valutabile).
Il risultato degli indicatori con oltre il 25% di casi missing è presentato in colore grigio e sottolineato.

Aggiornato 11 marzo 2022

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

2021 EUSOMA Indicators

Breast Centres Certification
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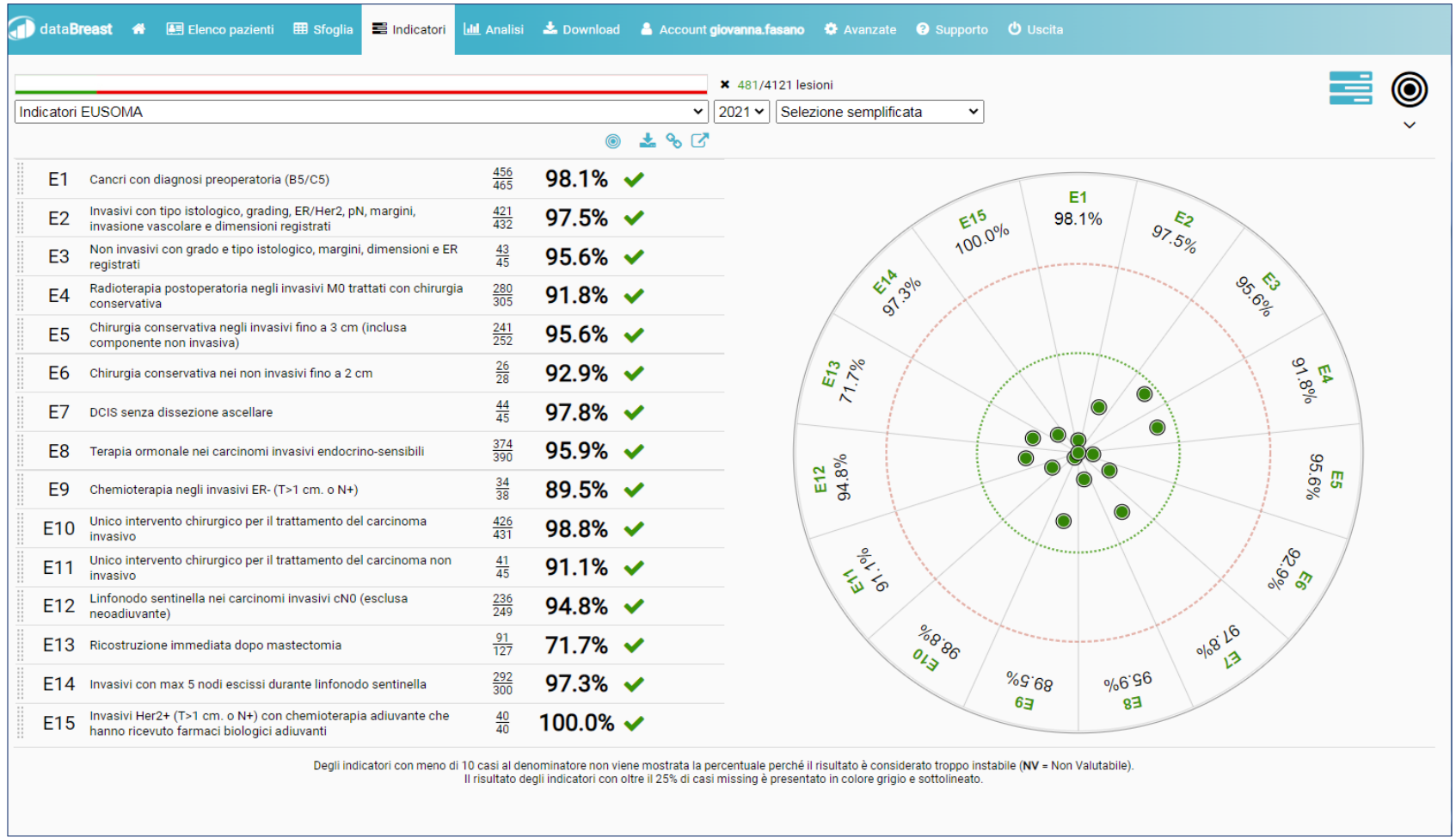

E1	Cancri con diagnosi preoperatoria (B5/C5)	456/465	98.1% ✔
E2	Invasivi con tipo istologico, grading, ER/Her2, pN, margini, invasione vascolare e dimensioni registrati	421/432	97.5% ✔
E3	Non invasivi con grado e tipo istologico, margini, dimensioni e ER registrati	43/45	95.6% ✔
E4	Radioterapia postoperatoria negli invasivi M0 trattati con chirurgia conservativa	280/305	91.8% ✔
E5	Chirurgia conservativa negli invasivi fino a 3 cm (inclusa componente non invasiva)	241/252	95.6% ✔
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E10	Unico intervento chirurgico per il trattamento del carcinoma invasivo	426/431	98.8% ✔
E11	Unico intervento chirurgico per il trattamento del carcinoma non invasivo	41/45	91.1% ✔
E12	Linfonodo sentinella nei carcinomi invasivi cN0 (esclusa neoadiuvante)	236/249	94.8% ✔
E13	Ricostruzione immediata dopo mastectomia	91/127	71.7% ✔
E14	Invasivi con max 5 nodi escissi durante linfonodo sentinella	292/300	97.3% ✔
E15	Invasivi Her2+ (T>1 cm. o N+) con chemioterapia adiuvante che hanno ricevuto farmaci biologici adiuvanti	40/40	100.0% ✔

Degli indicatori con meno di 10 casi al denominatore non viene mostrata la percentuale perché il risultato è considerato troppo instabile (**NV** = Non Valutabile).
Il risultato degli indicatori con oltre il 25% di casi missing è presentato in colore grigio e sottolineato.

Aggiornato 11 marzo 2022

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
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Follow-up Indicators

Breast Centres Certification
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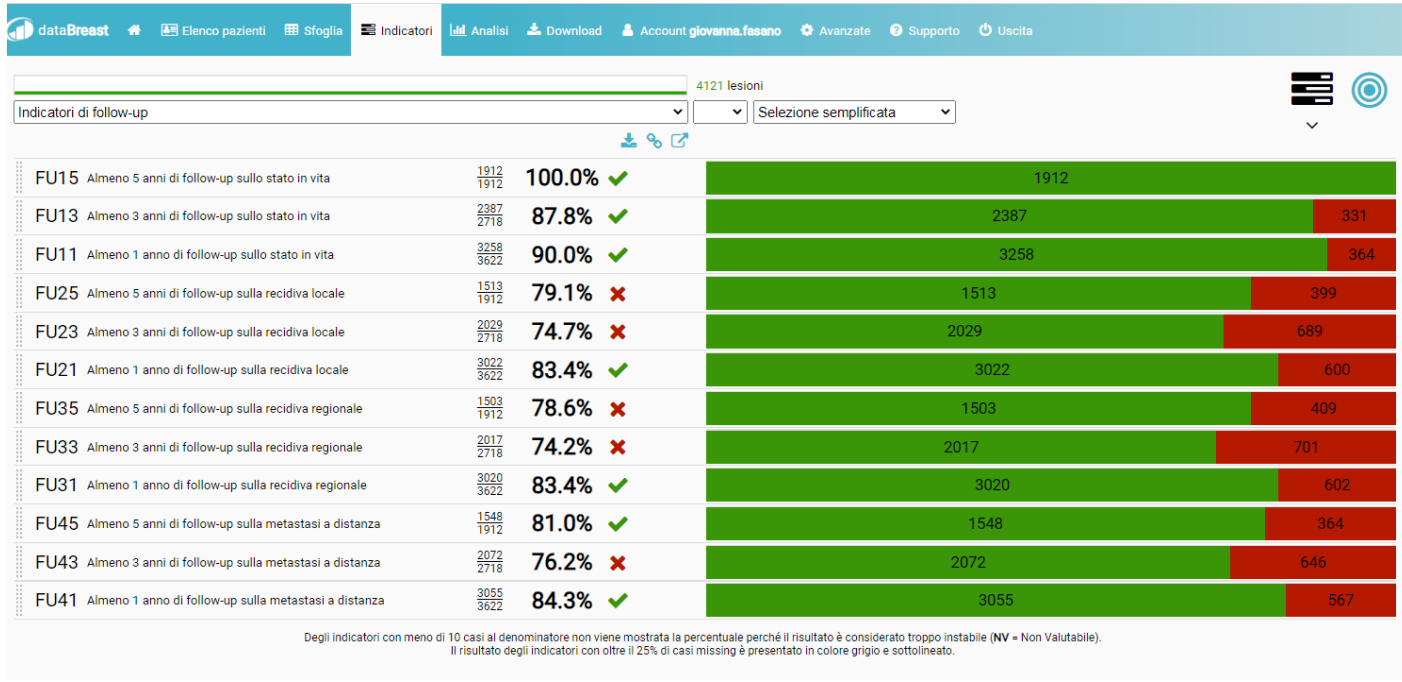
2021



FU15	Almeno 5 anni di follow-up sullo stato in vita	1912/1912	100.0% ✔	1912	
FU13	Almeno 3 anni di follow-up sullo stato in vita	2387/2718	87.8% ✔	2387	331
FU11	Almeno 1 anno di follow-up sullo stato in vita	3258/3622	90.0% ✔	3258	364
FU25	Almeno 5 anni di follow-up sulla recidiva locale	1513/1912	79.1% ✖	1513	399
FU23	Almeno 3 anni di follow-up sulla recidiva locale	2029/2718	74.7% ✖	2029	689
FU21	Almeno 1 anno di follow-up sulla recidiva locale	3022/3622	83.4% ✔	3022	600
FU35	Almeno 5 anni di follow-up sulla recidiva regionale	1503/1912	78.6% ✖	1503	409
FU33	Almeno 3 anni di follow-up sulla recidiva regionale	2017/2718	74.2% ✖	2017	701
FU31	Almeno 1 anno di follow-up sulla recidiva regionale	3020/3622	83.4% ✔	3020	602
FU45	Almeno 5 anni di follow-up sulla metastasi a distanza	1548/1912	81.0% ✔	1548	364
FU43	Almeno 3 anni di follow-up sulla metastasi a distanza	2072/2718	76.2% ✖	2072	646
FU41	Almeno 1 anno di follow-up sulla metastasi a distanza	3055/3622	84.3% ✔	3055	567

Degli indicatori con meno di 10 casi al denominatore non viene mostrata la percentuale perché il risultato è considerato troppo instabile (**NV** = Non Valutabile).
Il risultato degli indicatori con oltre il 25% di casi missing è presentato in colore grigio e sottolineato.

2020

9/2/2021 RomaSG2020.htm

Indicators 16 - Follow-up availability

	1 year	3 years	5 years		Minimum	Standard
Overall survival available	74.4%	37.8%	**28.0%**	<	80%	90%
Recurrence free survival available	64.5%	32.3%	**23.8%**	<	80%	90%
Regional LN recurrences free survival available	64.5%	32.1%	**23.4%**	<	80%	90%
Distant metastases free survival available	63.5%	34.2%	**25.5%**	<	80%	90%
Malignant cases	3110	2265	**1523**			
Earliest date of diagnosis	10/03/2000	10/03/2000	**10/03/2000**			
Latest date of diagnosis	06/02/2020	08/02/2018	**09/02/2016**			

Aggiornato 11 marzo 2022

Indicatori di Qualità - IV Stadio

MDM IV Stadio

- Almeno il 50% dei casi metastatici devono essere discussi in Conferenza Multidisciplinare (obiettivo iniziale)
- Al MDM devono essere presenti
  - Oncologo medico
  - Radioterapista
  - Infermiera di senologia
  - Radiologo
  - Anatomo patologo
  - Medico Nucleare
  - Specialista in cure palliative
  - Datamanager
- Le decisioni devono essere formalmente registrate in un verbale
- Le decisioni devono essere poi condivise con la paziente in presenza di una infermiera di senologia

Indicatori di Qualità - IV Stadio

- Almeno 25 casi/anno dovrebbe avere conferma istologica del sito metastatico con rivalutazione recettoriale e HER2
- Deve essere presente un Team specializzato, che include:
  - Oncologo medico
  - Infermiera di senologia
  - Assistente Sociale
  - Fisioterapista
  - Psico-oncologo
  - Medici specialisti
  - Terapista del dolore
  - Care Spirituale
  - Dietista
- Deve essere garantito un supporto alle famiglie delle pazienti (Standard ESMO Designated Centres of Integrated Oncology and Palliative Care)

Certificazione Euopea

Roma

3 marzo 2017

Breast Centres Certification

ITALCERT scheme in partnership with BCCERT

SISTEMA SANITARIO REGIONALE

AZIENDA OSPEDALIERA SAN GIOVANNI ADDOLORATA

Surveillance Visit BCCert

Roma

29 Marzo 2018

Breast Centres Certification

ITALCERT scheme in partnership with BCCERT

SISTEMA SANITARIO REGIONALE

AZIENDA OSPEDALIERA SAN GIOVANNI ADDOLORATA

Site Visit 2020

Actions taken

AUDIT REPORT

7 NON-CONFORMITIES

N°	Requirement	Classification Major/Minor	Doc Ref.	Motivation (e.g. missing evidence, evidence that the requirements has not been satisfied, there is compliance with the requirement but registration is missing)
1	The quality control of the mammography reading monitors must be performed	Major	4	Quality control of mammography reading monitors is not performed

8 RECOMMENDATIONS ON NON MANDATORY REQUIREMENTS

N°	Requirement	Doc Ref.	Motivation
1	The Breast Center should consider to replace the mammography Unit (Fuji) older than 10 years	4	Seen radiologic equipment
2	The use of triple assessment on the same day on new patients should be increased from 65% towards 100%	5	Actually only the 65% of the new patients
3	The radiologists are reading less than 3000 mammograms. Double reading is recommended	5	seen radiologists workload
4	The radiographer team should be enlarged so that all the mammograms could be done by experienced radiographers	4	seen radiographers workload

→ DONE

→ IMPLEMENTED – ARRIVING

→ IMPLEMENTED

→ IMPLEMENTED

→ IMPROVED

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

Breast Centres Certification

ITALCERT certification scheme, in partnership with BCCert

www.breastcentrescertification.com

CERTIFICATE No. 1034/00

We hereby certify that

Centro di Senologia

of

Complesso Ospedaliero San Giovanni Addolorata

Via dell'Amba Aradam, 9 - 00184 Roma

ITALY

Operative Units indicated in Annex 1 for the services listed

Is in compliance with the standard

Eusoma guidelines

"The requirements of a specialist Breast Centre"

This Certificate must be made public in integral form complete Annex 1

General Manager

Dr. Ing. Roberto Cusolito

First Issue Date
2017-05-19

Expire Date
2020-05-18

Annex 1 at Certificate No. 1034/00

Centro di Senologia

of

Complesso Ospedaliero San Giovanni Addolorata

List of Operative Units / Services

Services	Location Operative Unit
Breast Surgery Breast Reconstructive Surgery Breast Radiologist Breast Medical Oncology Breast Radiation Oncology Breast Pathology Breast Care Nursing Other services MDM Meeting	Complesso Ospedaliero San Giovanni Addolorata Via dell'Amba Aradam, 9 - 00184 Roma

The validity of this Annex is bound to that of the 1034/00 certificate

General Manager

Dr. Ing. Roberto Cusolito

2017-05-19

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SISTEMA SANITARIO REGIONALE
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Centro di Senologia

	2014	2015	2016	2017	2018	2019	2020	2021
N. Cancer Cases operated	327	357	411	428	492	459	522	572
Cases discussed at MDM	545	715	766	836	976	1075	1149	1228
Cases discussed at Stage IV MDM							39	102
Pre-Abilitation	0	46	236	310	363	229	2	
Genetic Consultation	0	71	97	178	304	405	323	303
BRCA tests	0	42	73	99	228	166	193	168
Psico-oncologist intervention	0	41	62	56	101	100	73	104
Dietitian (class and consultations)	0	0	62	66	216	242	110	120
Osteoporosis (Class and consultations)	0	0	23	49	59	102	40	40
Gynecology (Class and Consultations)	0	0	55	242	262	331	618	728
N. Patients in Trials	110	150	178	167	125	95	48	77
Ambulatory Visits at the Center	3283	3769	4390	5033	6128	6715	6993	7022

Grazie!

GRAZIE!

Grazie

Site Visit 2021

Actions taken

AUDIT REPORT

7 NON-CONFORMITIES

None

8 RECOMMENDATIONS ON NON MANDATORY REQUIREMENTS

N°	Requirement	Doc Ref.	Motivation
1	Breast Centre is recommended to continue improving compliance with Eusoma QI 16	4	Eusoma data report dated 09/02/2021

(*) *The non-compliance issued concerns the Eusoma Document edition 2020, but your Breast Centre is still certified with the Eusoma Document edition 2013: for this reason, if this finding is not managed correctly, your certification will not be suspended. However, we ask you to prepare for the transition and to better manage the improvement».*

9 OBSERVATIONS

N°	Description	Doc Ref.	Motivation
1	Visitors observe that the Breast Centre does not have a cumulative list of MDM attendance for all core team members	4	Discussion with the team
2	Visitors observe that training in communication has not yet undertaken for all core team members	4	Discussion with the team

10 POSITIVE ASPECTS

N°	Description
1	Visitors specially appreciated the way the Centre has prepared in advance for the 2020 requirements
2	Visitors specially appreciated the level of data management and bi-annual auditing
3	Visitors specially appreciate the sense of cohesion in the Breast Centre and the way they have continued development since start of certification process

IMPLEMENTED

IMPLEMENTED

IMPLEMENTED

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN GIOVANNI ADDOLORATA

Indicatori di Qualità - IV Stadio

Considerazioni

- In Europa, maggioranza delle pazienti al IV Stadio vengono ancora trattate fuori dai Centri di Senologia
- I Trattamenti oncologici sono complessi, spesso costosi, e la centralizzazione in Unità multidisciplinari può ottimizzare l'accesso e il rapporto costo-efficacia
- La Medicina Palliativa non può più essere considerata di secondo ordine, ma richiede spesso trattamenti integrati e coordinati

Metastasi Linfonodali Ascellari Controlaterali e Sopraclaveari

Ann Surg Oncol (2021) 28:2146–2154
https://doi.org/10.1245/s10434-020-09024-1

Annals of SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Treatment Patterns and Outcomes of Women with Breast Cancer and Supraclavicular Nodal Metastases

Nina P. Tamirisa, MD, MS[1], Yi Ren, MS[2], Brittany M. Campbell, MD[3], Samantha M. Thomas, MS[2], Oluwadamilola M. Fayanju, MS, MA, MPHS[2,4], Jennifer K. Plichta, MD, MS[2,4], Laura H. Rosenberger, MD, MS[2,4], Jeremy Force, DO[2,3], Terry Hyslop, PhD[2,5], E. Shelley Hwang, MD, MPH[2,4], and Rachel A. Greenup, MD, MPH[2,4]

[1]Department of Breast Surgical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX; [2]Duke Cancer Institute, Durham, NC; [3]Department of Medicine, Duke University School of Medicine, Durham, NC; [4]Department of Surgery, Duke University School of Medicine, Durham, NC; [5]Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC

ABSTRACT

Background. In 2002, breast cancer patients with supraclavicular nodal metastases (cN3c) were downstaged from AJCC stage IV to IIIc, prompting management with locoregional treatment. We sought to estimate the impact of multimodal therapy on overall survival (OS) in a contemporary cohort of cN3c patients.

Methods. Women ≥ 18 years with cT1-T4c/cN3c invasive breast cancer who underwent systemic therapy were identified from the 2004–2016 National Cancer Database. We compared three patient cohorts: (a) cN3c + multimodal therapy (systemic therapy, surgery, and radiation); (b) cN3c + non-standard therapy; and, (c) cM1. Logistic regression identified factors associated with receipt of multimodal therapy and Kaplan–Meier was used to estimate unadjusted OS. The Cox proportional hazards model estimated effects of diagnosis and treatment on OS after adjustment.

Results. Overall, 1827 (3.7%) patients with cN3c disease and 46,919 (96.3%) cM1 patients were identified. Of cN3c patients, 74.5% ($n = 1362$) received multimodal therapy and 25.5% ($n = 465$) received non-standard therapy; receipt of multimodal therapy was associated with improved 5-year OS (multimodal: 59% vs. M1: 28% vs. non-standard: 28%, log-rank $p < 0.001$). Adjusting for covariates, non-standard therapy was associated with an increased risk of death compared with receipt of multimodal therapy (HR 2.20, 95% CI 1.71–2.83, $p < 0.001$). Private insurance was the only patient characteristic associated with a greater likelihood of receiving multimodal therapy (OR 2.81; 95% CI, 1.64–4.82; $p < 0.001$).

Conclusion. Women with cN3c breast cancer who received multimodal therapy demonstrated improved overall survival when compared with patients undergoing non-standard therapy and those with metastatic (M1) disease. Although selection bias may contribute to worse overall survival among cN3c patients undergoing non-standard therapy, national guidelines should encourage locoregional treatment in carefully selected patients.

Contemporary staging guidelines for breast cancer are used to categorize women for the purpose of prognostication and to guide oncologic therapy; however, in the clinical setting, patients present on a spectrum from early stage to metastatic disease.[1–3] Extensive ipsilateral nodal involvement without evidence of distant metastases presents a particular treatment challenge, as the value of locoregional therapy in these patients remains uncertain. In 2002, studies demonstrating an improved survival with receipt of comprehensive multimodal therapy prompted the American Joint Commission on Cancer (AJCC) to downstage breast cancer with supraclavicular nodal metastases (cN3c) from stage IV to IIIc disease.[4–6] Reflecting this change, the National Comprehensive Cancer Network (NCCN) guidelines recommended these individuals be

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Annals of SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Contralateral Axillary Lymph Node Metastases from Breast Carcinoma: Is it Time to Review TNM Cancer Staging?

Francesca Magnoni, MD, PhD[1], M. Colleoni, MD[2], D. Mattar, MD[1], G. Corso, MD, PhD[1,3], V. Bagnardi, PhD[4], S. Frassoni, MSc[4], G. Santomauro, Mrs[5], B. A. Jereczek-Fossa, MD, PhD[3,6], P. Veronesi, MD, PhD[1,3], V. Galimberti, MD[1], V. Sacchini, MD, PhD[1,3], and M. Intra, MD[1]

[1]Division of Breast Cancer Surgery, IEO, European Institute of Oncology, IRCCS, Milan, Italy; [2]Division of Breast Cancer Medical Treatments, IEO, European Institute of Oncology, IRCCS, Milan, Italy; [3]Faculty of Medicine, University of Milan, Milan, Italy; [4]Department of Statistics and Quantitative Methods, University of Milan-Bicocca, Milan, Italy; [5]Service of Data Management, IEO, European Institute of Oncology, IRCCS, Milan, Italy; [6]Division of Radiotherapy, IEO, European Institute of Oncology, IRCCS, Milan, Italy

ABSTRACT

Background. Contralateral axillary lymph node metastasis (CAM) is an infrequent clinical condition currently considered an M1, stage IV, disease. Due to the absence of shared data on CAM significance and on its therapeutic approach, be it curative or simply palliative, its management is still uncertain and undoubtedly represents a clinical challenge.

Patients and Methods. Patients with pathologically confirmed metachronous CAM were retrospectively evaluated. All patients had been managed at the European Institute of Oncology, Milan, Italy, from 1997. Patients with distant metastases at the time of CAM were excluded. Possible treatments included surgery, systemic therapy and RT (radiotherapy). Outcomes were evaluated as rates of disease-free survival (DFS) and of overall survival (OS).

Results. Forty-seven patients with CAM were included in the study. Metachronous CAM occurred 73 months (range 5–500 months) after diagnosis of the primary tumor. The median follow-up time was 5.4 years (interquartile range 2.9–7.0 years). The estimated OS was 72% at 5 years (95% CI 54–83), and 61% at 8 years (95% CI 43–75). The estimated DFS was 61% at 5 years (95% CI 44–74), and 42% at 8 years (95% CI 25–59).

Conclusion. These findings, together with those from previous studies, show that CAM outcome, particularly if measured as OS, appear better than at other sites of distant dissemination, when CAM is subjected to surgical and systemic treatments with a curative intent. Therefore, a new clinical scenario is suggested where, in the TNM system, CAM is no longer classified as a stage IV, but as an N3 disease.

Contralateral axillary lymph node metastasis (CAM) is an infrequent clinical condition with a reported incidence of between 1.9 and 6%.[1] It can originate from three different clinical conditions: (a) metastasis from extra-mammary sites, such as gynecological, gastrointestinal, pulmonary, and cutaneous primary cancer, or lymphoma and melanoma; (b) metastasis from an occult ipsilateral primary breast cancer; (c) contralateral dissemination from primary breast cancer.[1–3] This last condition can lead to two different types of CAM: synchronous, if CAM occurs at the same time of diagnosis of the index breast cancer; or metachronous, if CAM appears after the previous breast primitiveness has been subjected to adjuvant treatment. At times, metachronous CAM appears simultaneously with an ipsilateral breast cancer recurrence (IBCR), while in other cases it is not accompanied by IBCR.

The origin of CAM may vary in relation to the source of the metastatic disease. Especially in patients who have previously undergone breast or axilla surgery plus radiotherapy (RT), lymph drainage to contralateral nodal basins, such as contralateral axillae, internal mammary chain or

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Metanalisi degli Studi prospettici

Contents lists available at ScienceDirect

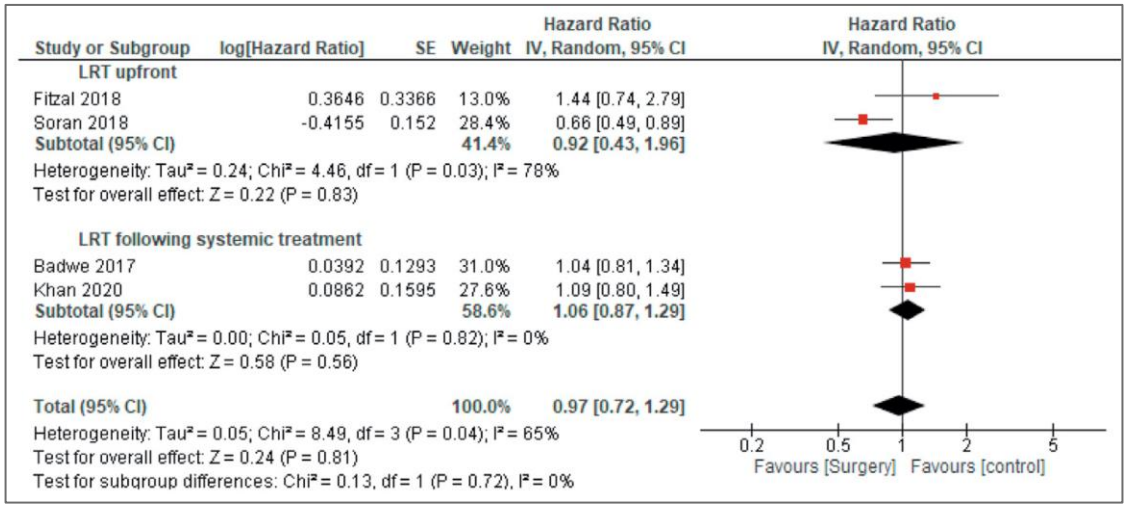
The Breast

journal homepage: www.elsevier.com/brst

Locoregional therapy in de novo metastatic breast cancer: Systemic review and meta-analysis

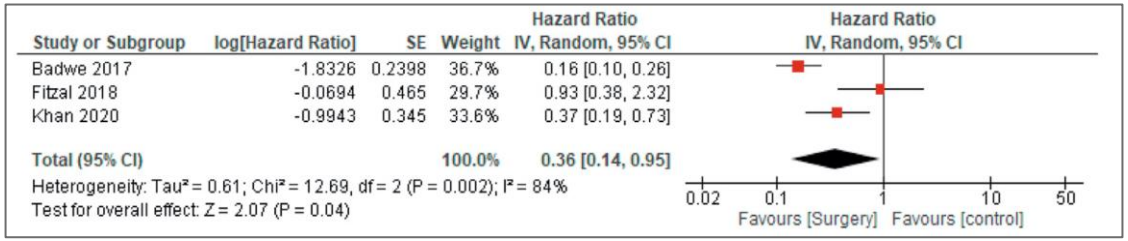
Daniel Reinhorn [a], Raz Mutai [a], Rinat Yerushalmi [a, b], Assaf Moore [a, b], Eitan Amir [c], Hadar Goldvaser [d, e, *]

Overall Survival



- ✓ Metanalisi di 4 trials prospettici
- ✓ 970 pazienti

Time to loco-regional Progression



Reinhorn D, et al: The Breast 2021; 58: 171-183

Studio NCDB- Propensity Score Macthed

THE IMPACT OF PRIMARY TUMOR SURGERY ON SURVIVAL IN HER2 POSITIVE STAGE IV BREAST CANCER PATIENTS IN THE CURRENT ERA OF TARGETED THERAPY

Ross Mudgway BS, Carlos Chavez de Paz Villanueva MD MPH, Ann C. Lin MD, Maheswari Senthil MD, Carlos A. Garberoglio MD, Sharon S. Lum MD

LOMA LINDA UNIVERSITY School of Medicine

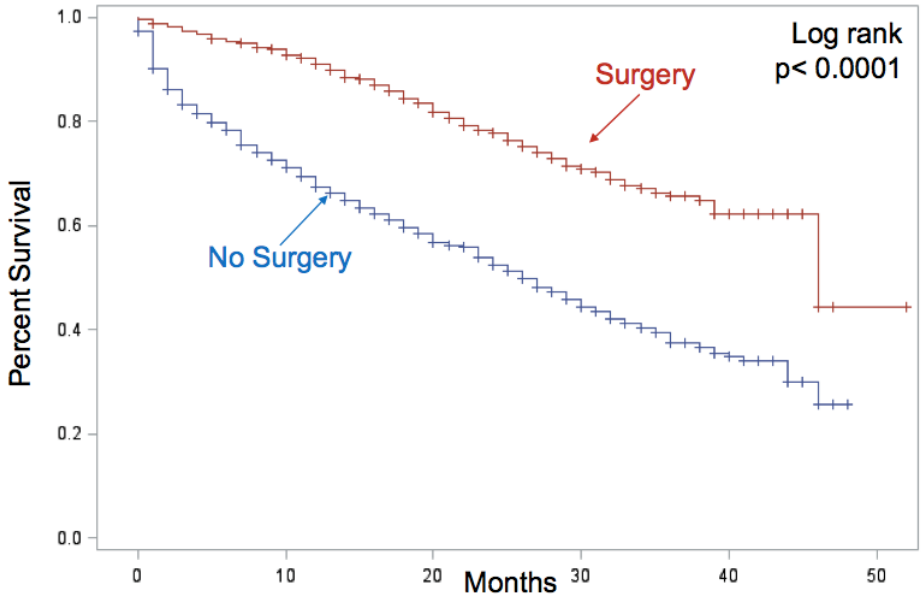
Commission on Cancer® NCDB

AACR American Association for Cancer Research FINDING CURES TOGETHER

Propensity matched overall survival

Surgery was associated with improved survival

- Median follow-up = 21.2 (0-52) months
- Median survival:
  - Surgery: 25 months
  - No Surgery: 18 months
    - p = .0001
- HR 0.56 (95% CI 0.40-0.77)
  - p = 0.0004



- ✓ NCDB (2.807.541 casi)
- ✓ 58.867 NEU +
- ✓ 2010-2012
- ✓ 3231 pazienti stadio IV incluse nello studio

Courtesy Sharon S Lum, Loma Linda University, 2019

SISTEMA SANITARIO REGIONALE AZIENDA OSPEDALIERA SAN GIOVANNI ADDOLORATA

Meta-analisi studi retrospettivi

Breast Cancer Res Treat (2010) 120:9–16
DOI 10.1007/s10549-009-0670-0

REVIEW

Impact of breast surgery on survival in patients with distant metastases at initial presentation: a systematic review of the literature

Jetske Ruiterkamp · Adri C. Voogd · Koop Bosscha · Vivianne C. G. Tjan-Heijnen · Miranda F. Ernst

Received: 30 September 2009 / Accepted: 25 November 2009 / Published online: 13 December 2009

Abstract According to current treatment standards, patients with metastatic breast cancer at diagnosis receive palliative therapy. Local treatment of the breast is only recommended if the primary tumor is symptomatic. Recent studies suggest that surgical removal of the primary tumor has a favorable impact on the prognosis of patients with primary metastatic breast cancer. We performed a systematic review of the literature to weigh the evidence for and against breast surgery in this patient group. Ten retrospective studies were found in which the use of breast surgery in primary metastatic breast cancer and its impact on survival was examined. The hazard ratios of the studies were pooled to provide an estimate of the overall effect of surgery, and the results and conclusions of the studies were analyzed. A crude analysis, without adjustment for potential confounders, showed that surgical removal of the breast lesion in stage-IV disease was associated with a significantly higher overall survival rate in seven of the ten studies, and a trend toward a better survival in the three remaining studies. Surgery of the primary tumor appeared to be an independent factor for an improved survival in the multivariate analyses from the individual studies, with hazard ratios ranging from 0.47 to 0.71. The pooled hazard ratio for overall mortality was 0.65 (95% CI 0.59–0.72) in favor of the patients undergoing surgery. This systematic review of the literature suggests that surgery of the primary breast tumor in patients with stage-IV disease at initial presentation does have a positive impact on survival. In order to provide a definite answer on whether local tumor control in patients with primary metastatic disease improves survival, a randomized controlled trial comparing systemic therapy with and without breast surgery is needed.

Keywords Surgery · Local therapy · Breast cancer · Primary metastatic

Introduction

About 11% of all women in the western world will develop breast cancer. Of all breast cancer patients 3–10% has distant metastases at initial presentation [1]. Median survival of these patients is in the range of 16–24 months and is determined by several factors, including number and site of metastatic lesions, and tumor characteristics such as hormone receptor and HER2neu status [2, 3]. During the last decades, the treatment of metastatic breast cancer has undergone considerable changes, with taxanes and third-generation aromatase-inhibitors being introduced in the nineties of the previous century and, among others, trastuzumab and bevacizumab in the current decade [4–6].

Until now, we continue to adhere to the concept that metastatic breast cancer is an incurable disease. In line with this concept, aggressive local therapy is thought to provide no survival advantage, and the primary goals of local treatment are the prevention or palliation of symptoms. Therefore, local treatment of the primary tumor is only

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Med Oncol (2012) 29:3282–3290
DOI 10.1007/s12032-012-0310-0

REVIEW ARTICLE

Surgery of primary tumors in stage IV breast cancer: an updated meta-analysis of published studies with meta-regression

Fausto Petrelli · Sandro Barni

Received: 10 July 2012 / Accepted: 14 July 2012 / Published online: 28 July 2012

Abstract Systemic therapy is the mainstream treatment of stage IV breast cancer. Surgical excision of the primary breast cancer tumor in the presence of synchronous metastatic disease is debated, but a shared indication is not proposed by current guidelines. The purpose of this analysis is to aggregate the published survival data of surgery of an intact primary tumor in stage IV disease. The authors searched PubMed for publications reporting data about the survival benefit of surgery of the primary tumor in patients with metastatic breast cancer. Hazard ratios for survival when reported after multivariate analysis (with 95 % confidence intervals) were obtained from publications and pooled in a meta-analysis. A meta-regression weighted for the extent of disease, ER/HER2 status, age, visceral or bone disease, rate of radiotherapy, and systemic therapies offered was performed. A total of 15 publications were included in this meta-analysis. Surgery of the primary tumor appeared to be an independent factor for an improved survival in the multivariate analyses from the individual studies, with an HR of 0.69 ($p < 0.00001$). According to meta-regression, the survival benefit was independent of age, extent, site of the metastatic disease, and HER2 status, but was directly proportional to the rate of patients exposed to systemic therapies and radiotherapy and inversely correlated with the ER+ status of the population included. Surgery of the primary tumor in stage IV breast cancer seems to offer a survival benefit in metastatic patients, in particular when it is offered in a multimodality treatment program.

Keywords Surgery · Primary tumor · Metastatic breast cancer · Survival

Metastatic breast cancer (MBC) is defined as the dissemination of tumor cells beyond the breast, chest wall, and regional lymph nodes. Treatment of MBC is not usually considered curative, but a small niche of patients, with limited and indolent sites of metastatic disease other than sensitivity to treatment, may experience very long survivals. This gain survival has been reached with better chemotherapy and targeted therapies in particular. The treatment goals in stage IV disease are prolongation of survival, control of burden of disease, reduction in cancer-related symptoms or complications, and maintenance of quality of life. These objectives are usually obtained with systemic therapies (e.g., endocrine therapy, chemotherapy, or biological agents) and in some circumstances with locoregional treatments (e.g., radiotherapy for painful bone lesions or surgery for solitary nodal, lung, or liver metastasis). There is a subset of women with MBC who have limited systemic tumor spread and a biologically indolent disease. Between 5 and 10 % of patients with stage IV disease survive five or more years, and 2–5 % become long-term survivors [1, 2]. These long-term survivors tend to be young, with an excellent performance status and limited metastatic (sometimes referred to as oligometastatic) disease. For such patients, combined modality approaches, often including surgery, appear to provide more hope for long-term progression-free survival than chemotherapy alone.

Primary breast cancer (BC) showing synchronous, distant metastases at presentation is present in a small percentage (3–4 %) in all BC patients, in which both the distant and locoregional controls of disease are endpoints

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Accepted Manuscript

Primary Tumor Resection in Stage IV Breast Cancer: A Systematic Review and Meta-analysis

Weikai Xiao, MD, Yutian Zou, MD, Shaoquan Zheng, MD, Xiaoqian Hu, BSc, Peng Liu, MD, Xinhua Xie, MD, Ping Yu, MD, Hailin Tang, MD, PhD, Xiaoming Xie, MD, PhD

PII: S0748-7983(18)31269-1
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Reference: YEJSO 5050

To appear in: *European Journal of Surgical Oncology*

Received Date: 28 May 2018
Revised Date: 30 July 2018
Accepted Date: 1 August 2018

	No. of studies	No. of patients	Hazard ratios	p	I^2 (%)
RCTs					
Trials with ⩾ 3y of follow- up[53]	1	274	0.66 (0.49, 0.89)	0.006	/
Surgery after responding to chemotherapy[6]	1	350	1.04 (0.81, 1.34)	0.79	/
Observational studies					
Overall	30	67272	0.65 (0.61, 0.70)	<0.001	80
Studies with ⩾ 2 y of follow- up	19	31315	0.61 (0.54, 0.68)	<0.001	81
Studies with ⩾ 3 y of follow- up	10	29374	0.62 (0.55, 0.71)	<0.001	83
Studies with ⩾ 4 y of follow- up	2	848	0.56 (0.48, 0.64)	<0.001	0
Hormone-receptor positive	2	NA	0.65 (0.47, 0.91)	0.01	0
Hormone-receptor negative	2	NA	0.54 (0.32, 0.92)	0.02	0
No. of metastases = 1	4	NA	0.62 (0.48, 0.81)	<0.001	24
No. of metastases ⩾3	3	NA	0.98 (0.44, 2.15)	0.95	0
Bone-only metastases	3	NA	0.61 (0.37, 1.00)	0.05	31
Visceral-only metastasis	2	NA	0.58 (0.28, 1.20)	0.14	24
Negative margin	3	8379	0.61 (0.58, 0.65)	<0.001	0
Positive margin	3	7544	0.84 (0.67, 1.05)	0.13	60
Surgery prior to systemic therapy	2	18608	0.79 (0.57, 1.10)	0.16	94
Surgery following systemic therapy	1	19463	0.56 (0.52, 0.61)	<0.001	/

Ruiterkamp et al: Breast Cancer Res Treat 2010; 120: 9-16

Petrelli F et al: Med Onocol 2012; 29: 3382-3290

Xiao W et al: EJSO 2018; 44: 1504-1512

Stadio IV »de novo»

- 5-6% dei tumori della mammella
- Circa 3500 donne /anno in Italia
- 25% dei casi allo stadio IV
- Metastasi ossee rappresentano il 50% delle lesion metastatiche concomitanti alla diagnosi

	Tema
1	Chirurgia e malattia al IV Stadio
2	Processo di Certificazione Europea
3	Indicatori di Qualità
4	Esperienza sul campo
5	Parametri per le donne al IV stadio
6	Conclusioni

Trials Randomizzati

Country	Accrual Period	N Projected	N Accrual	Initial Therapy	Status
India (Tata Memorial)	2005-12	350	350	Systemic Therapy	Published
Turkey (MF 07-01)	2008-12	271	274	Surgery	Published
USA and Canada ECOG 2108	2011-16	880	368	Systemic Therapy	Published
Japan JCOG 1017	2011-18	500	400	Systemic Therapy	Completed
Austria (ABCSG 28) (POSYTIVE)	2010-15	254	90	Surgery	Early Stopped
Netherlands (SUBMIT)	2011-16	516	0	Surgery	Early Stopped

Gli studi retrospettivi favoriscono la chirurgia

Breast Cancer Res Treat (2010) 120:9–16
DOI 10.1007/s10549-009-0670-0

REVIEW

Impact of breast surgery on survival in patients with distant metastases at initial presentation: a systematic review of the literature

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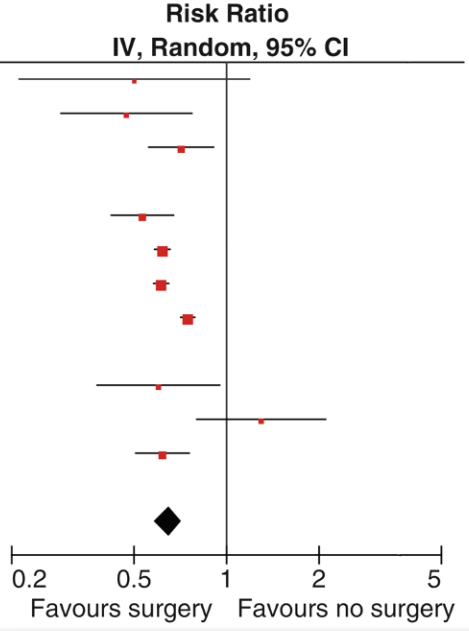
Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Random, 95% CI
Babiera et al. 2006	-0.69	0.44	1.3%	0.50 [0.21, 1.19]
Bafford et al. 2009	-0.75	0.25	3.5%	0.47 [0.29, 0.77]
Blanchard et al. 2007	-0.34	0.124	9.4%	0.71 [0.56, 0.91]
Cady 2008	0	0		Not estimable
Fields 2007	-0.63	0.119	9.8%	0.53 [0.42, 0.67]
Gnerlich 2007	-0.48	0.029	19.0%	0.62 [0.58, 0.65]
Khan 2002 (1)	-0.49	0.029	19.0%	0.61 [0.58, 0.65]
Khan 2002 (2)	-0.29	0.027	19.1%	0.75 [0.71, 0.79]
Leung 2009	0	0		Not estimable
Rapiti 2006 (1)	-0.51	0.234	3.9%	0.60 [0.38, 0.95]
Rapiti 2006 (2)	0.26	0.246	3.6%	1.30 [0.80, 2.10]
Ruiterkamp 2009	-0.48	0.102	11.3%	0.62 [0.51, 0.76]
Total (95% CI)			**100.0%**	**0.65 [0.59, 0.72]**

Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 47.04$, df = 9 ($P < 0.00001$); $I^2 = 81\%$
Test for overall effect: $Z = 8.38$ ($P < 0.00001$)

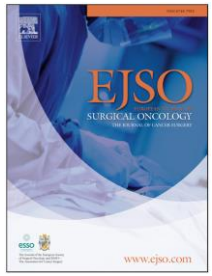


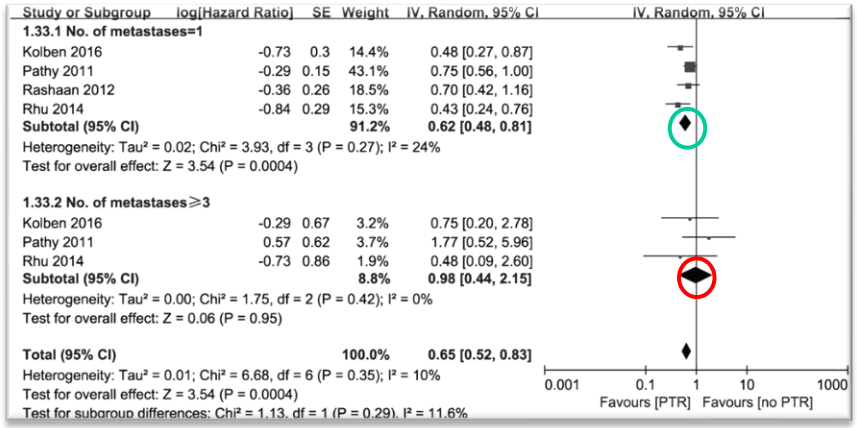
Ruiterkamp J et al: Breast Cancer Res Treat 2010; 120: 9-16

Gli studi retrospettivi favoriscono la chirurgia

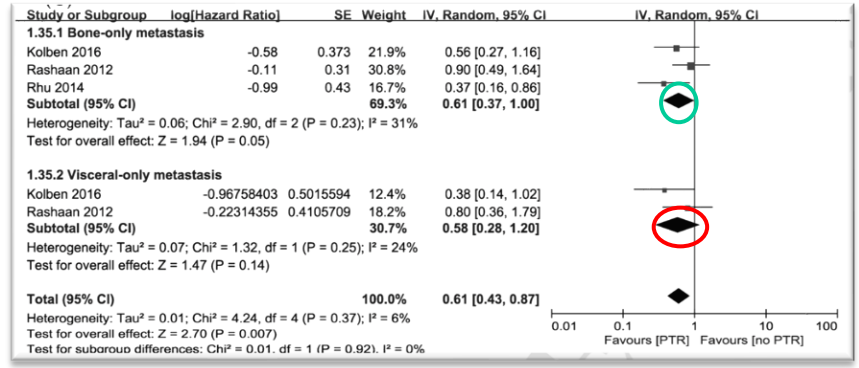
Primary Tumor Resection in Stage IV Breast Cancer: A Systematic Review and Meta-analysis

Weikai Xiao, MD, Yutian Zou, MD, Shaoquan Zheng, MD, Xiaoqian Hu, BSc, Peng Liu, MD, Xinhua Xie, MD, Ping Yu, MD, Hailin Tang, MD, PhD, Xiaoming Xie, MD, PhD





Numero di Metastasi



Tipo di Metastasi

Xiao W et al: EJSO 2018; 44: 1504-1512

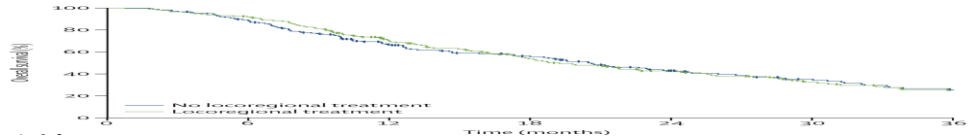
Conclusioni

- E' possible considerare la chirurgia come trattamento "non-standard" in alcuni casi selezionati ?
  - ✓ Buona risposta nel sito metastatico/non risposta del primario
  - ✓ "At least One positive" (ER+/HER2+), in risposta
  - ✓ Minimal Stage IV

➢ Cosa succede per le donne con risposta completa

➢ Practice pattern per Margini, RT, linfonodi

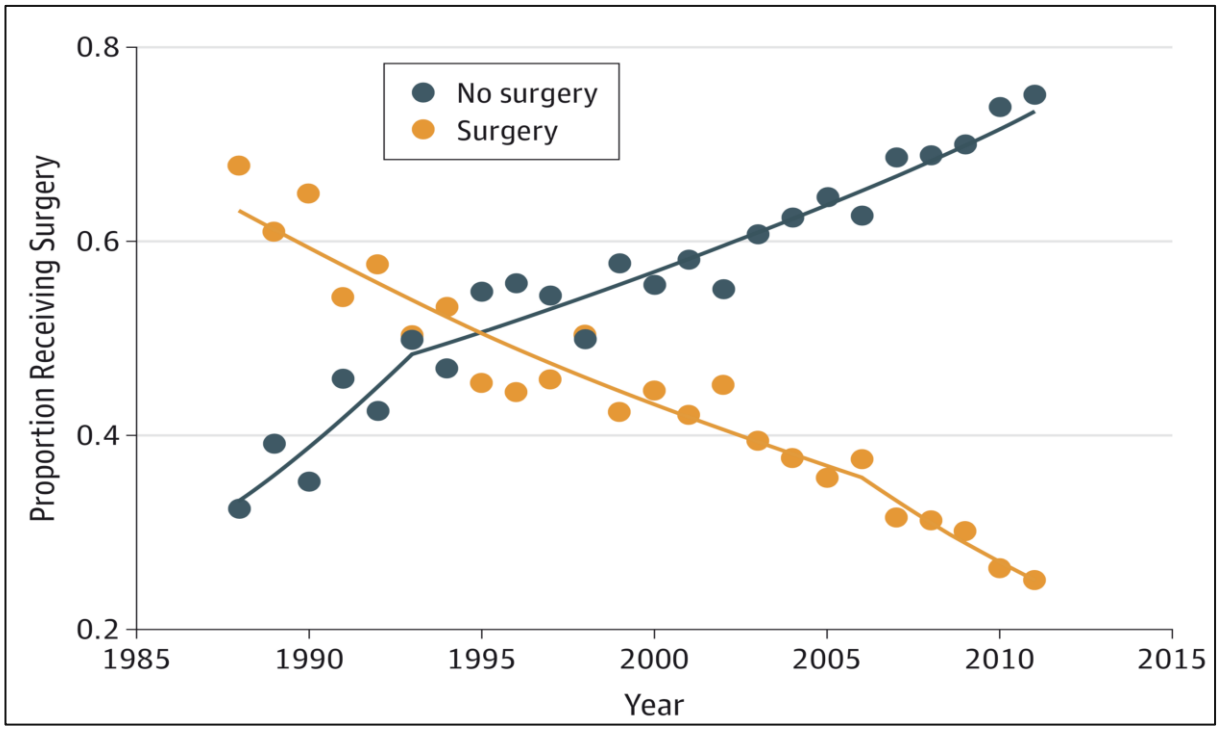
Turkish Trial MF07-01



Randomized Trial Comparing Resection of Primary Tumor with No Surgery in Stage IV Breast Cancer at Presentation: Protocol MF07-01

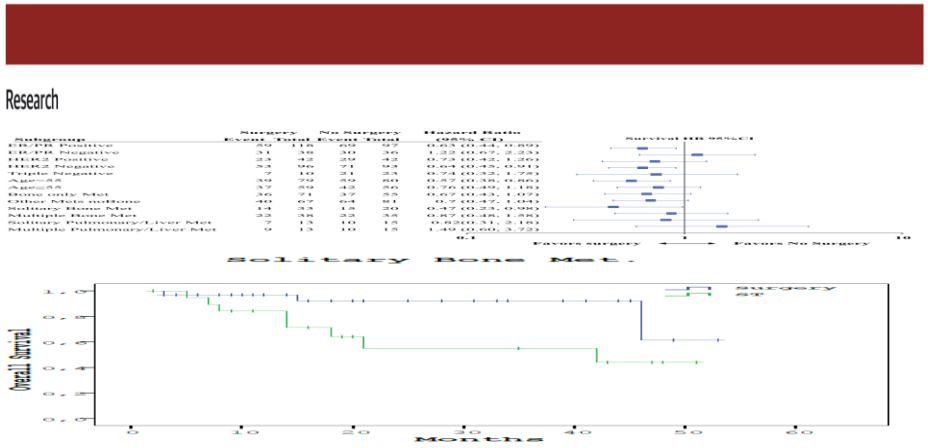
Lancet Oncol 2015

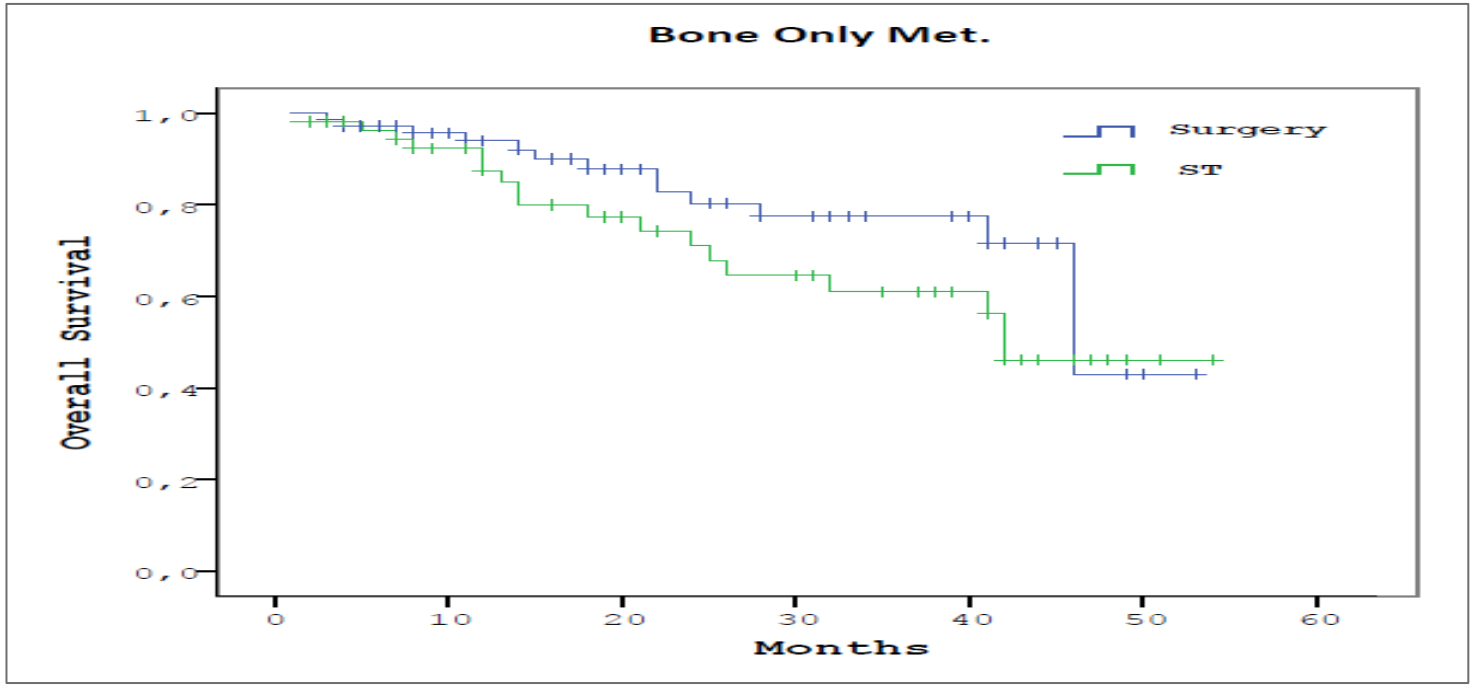
Published Online
September 10, 2015
http://dx.doi.org/10.1016/
S1470-2045(15)00135-7



Soran A: Ann Surg Oncol 2018; 25: 3141-3149

Studio Propettico Turco (BOMET MF 14-01)





- ✓ Prospective, multicenter Registry Study
- ✓ 2014-
- ✓ 505 pazienti
- ✓ Stage IV de novo
- ✓ Bone Mets only
- ✓ Median F/U 34 months

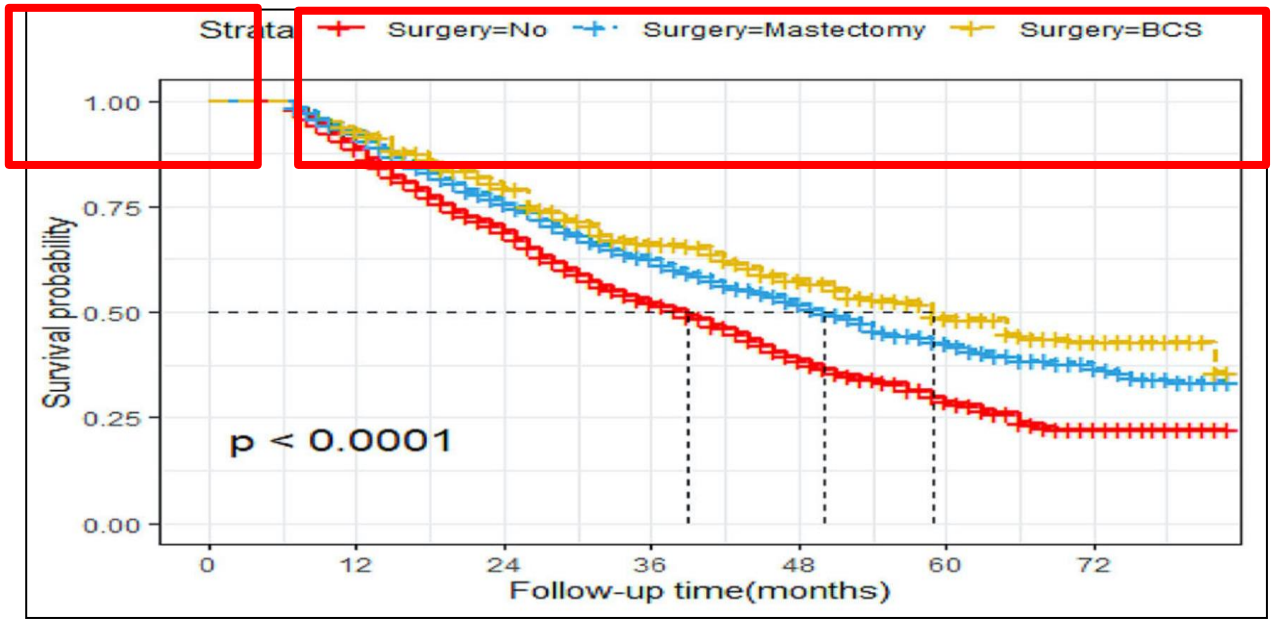
Doran A, et al: Ann Surg Oncol 2021; 28: 5048-5057

Studio Multicentrico Francese

[1] Department of Breast Surgery, First Affiliated Hospital, Xi'an Jiaotong University, Xi'an, China, [2] School of Medicine, Xi'an Jiaotong University, Xi'an, China

Kunlong Li[1,2†], Can Zhou[1†], Yan Yu[1], Ligang Niu[1], Wei Zhang[1], Bin Wang[1], Jianjun He[1*] and Guanqun Ge[1*]

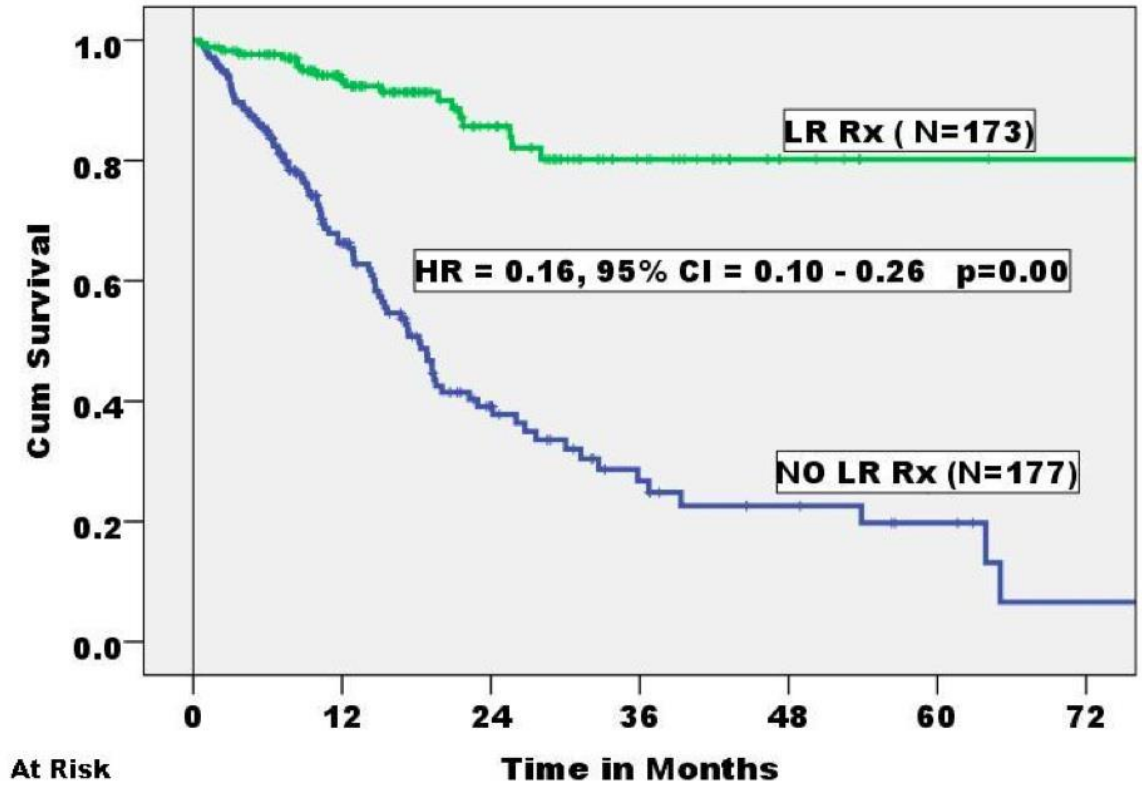
Metastatic Pattern Discriminates Survival Benefit of Type of Surgery in Patients With *De Novo* Stage IV Breast Cancer Based on SEER Database



- ✓ French Metastatic DB
- ✓ N = 4276
- ✓ 2008-2014

Pons-Tostivint E et al: Ann Surg Oncol 2019; 26: 356-365

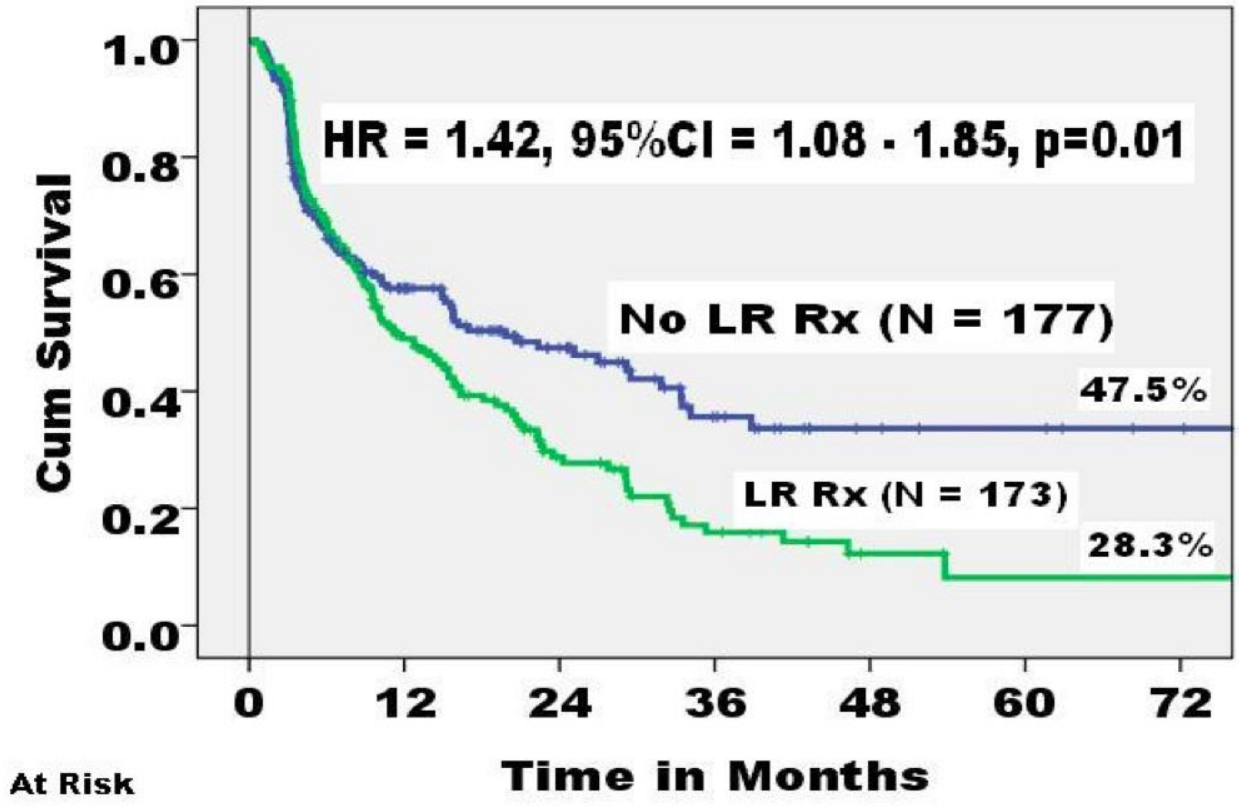
Local Progression-free Survival
Tata Memorial Trial



Tata Memorial; Badwe RA et al: San Antonio Breast Cancer Conference 2014. With Permission

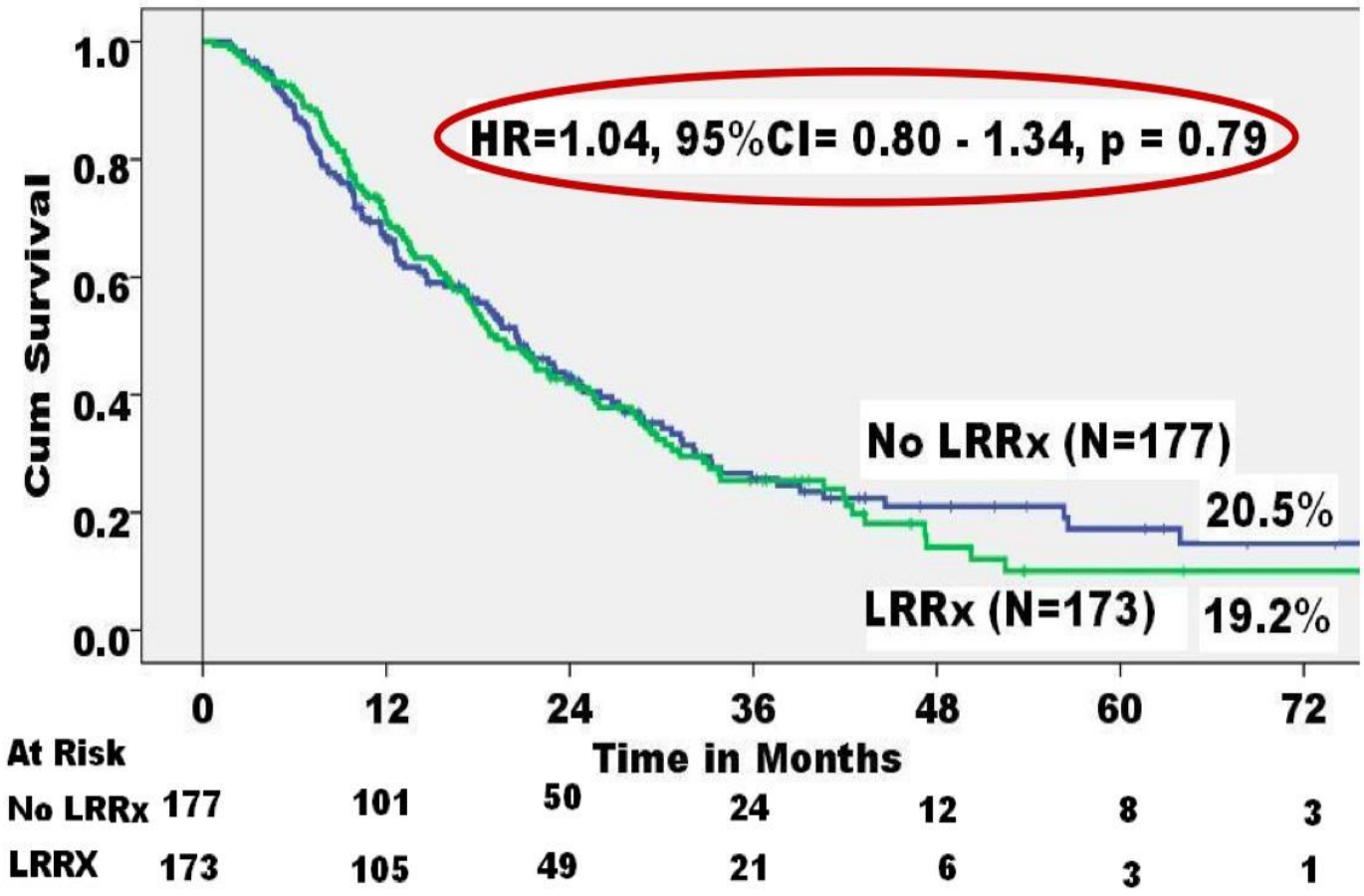
Distant Progression-free Survival

Tata Memorial Trial



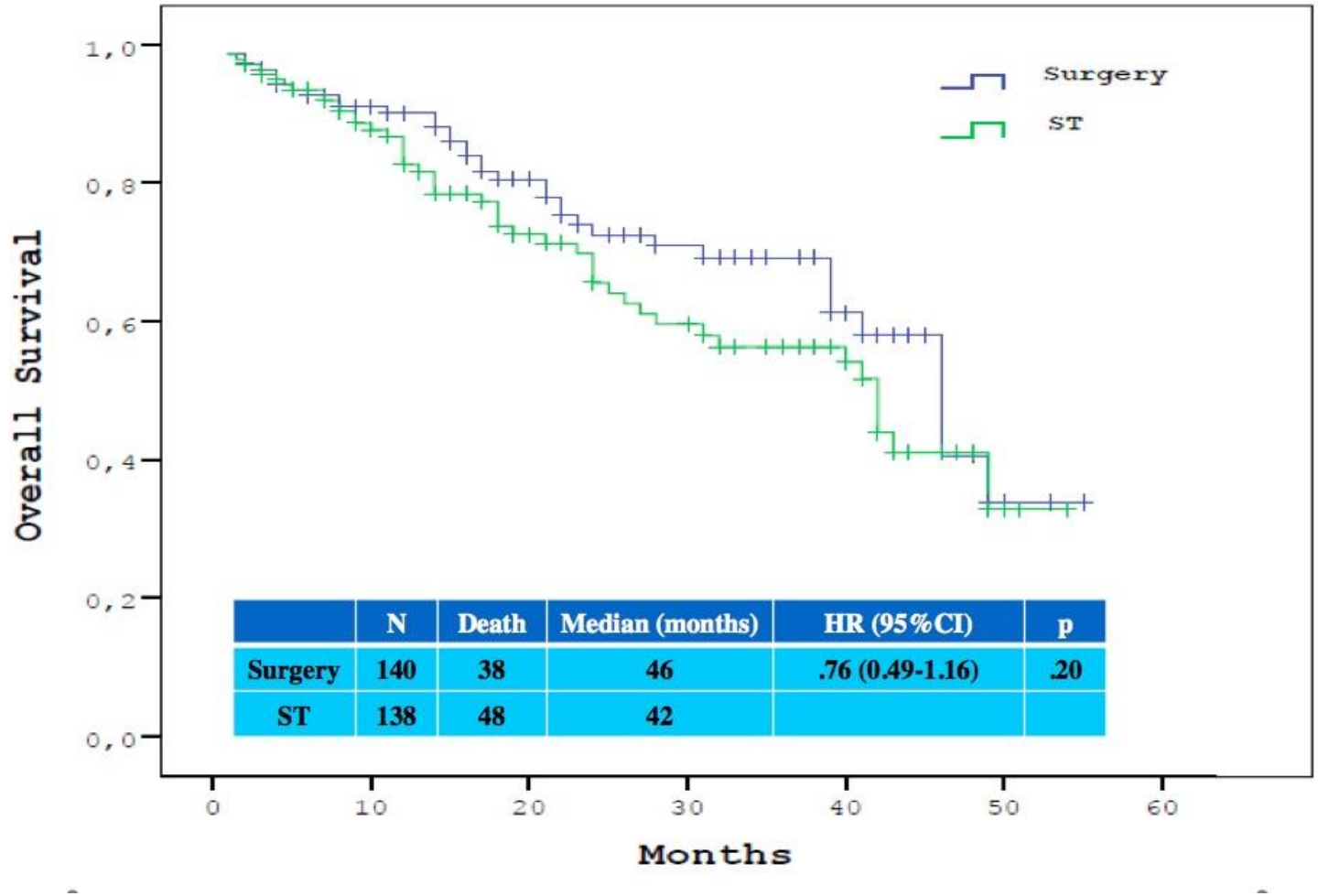
Tata Memorial; Badwe RA et al: San Antonio Breast Cancer Conference 2014. With Permission

Survival
Tata Memorial Trial



Tata Memorial; Badwe RA et al: San Antonio Breast Cancer Conference 2014. With Permission

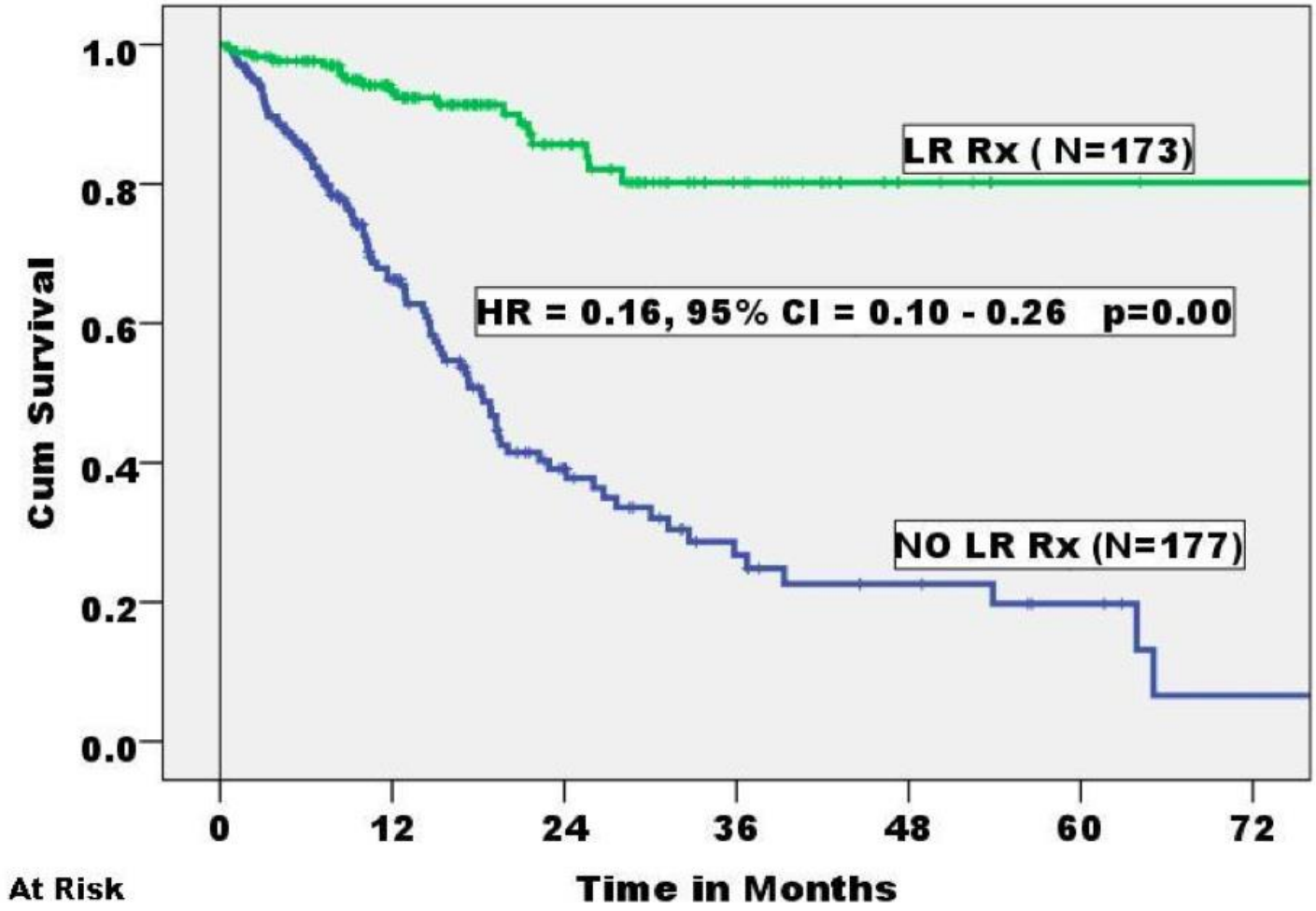
Turkish Trial MF07-01



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

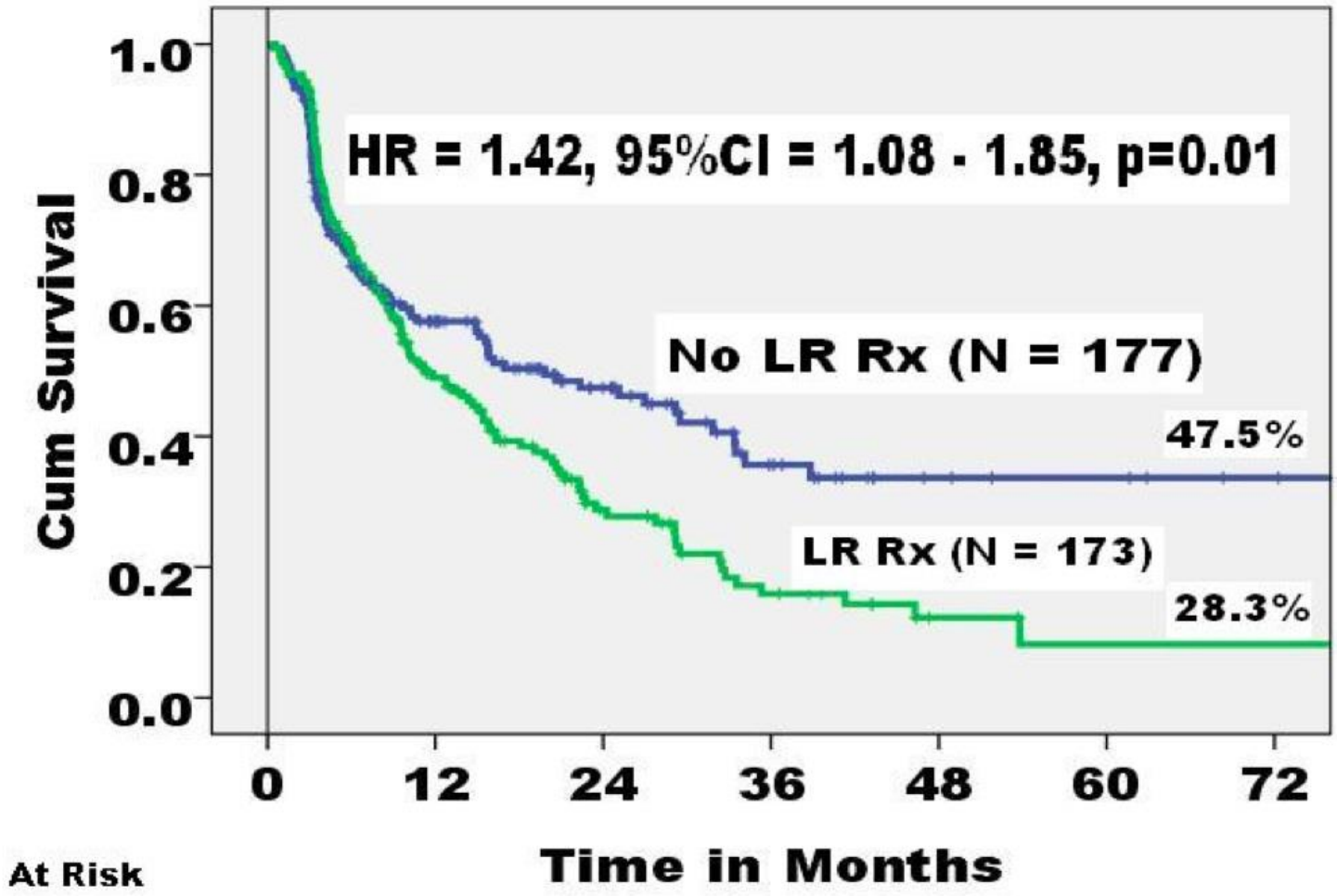
Soran A et al: San Antonio Breast Cancer Conference 2013, With Permission

Turkish Trial MF07-01

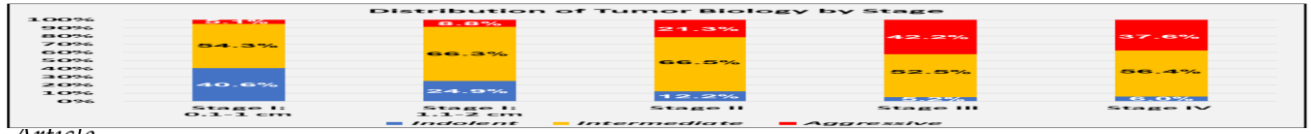


Soran A et al: San Antonio Breast Cancer Conference 2014, With Permission

Turkish Trial MF07-01



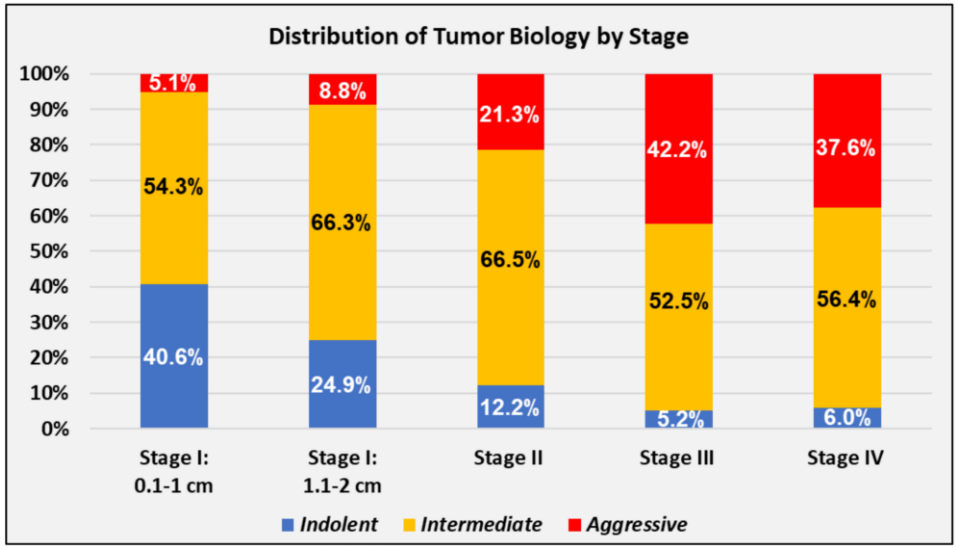
Soran A et al: San Antonio Breast Cancer Conference 2014, With Permission

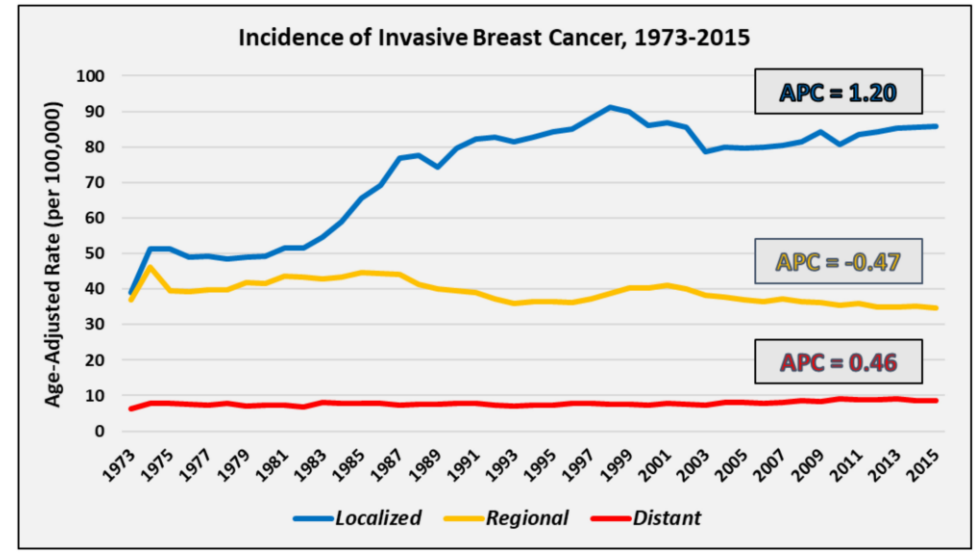


Article

Why Has Breast Cancer Screening Failed to Decrease the Incidence of de Novo Stage IV Disease?

Danielle R. Heller [1], Alexander S. Chiu [1], Kaitlin Farrell [2], Brigid K. Killelea [2] and Donald R. Lannin [2,*]





Metanalisi degli Studi prospettici

Ann Surg Oncol
https://doi.org/10.1245/s10434-018-6494-6

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

CrossMark

ORIGINAL ARTICLE – BREAST ONCOLOGY

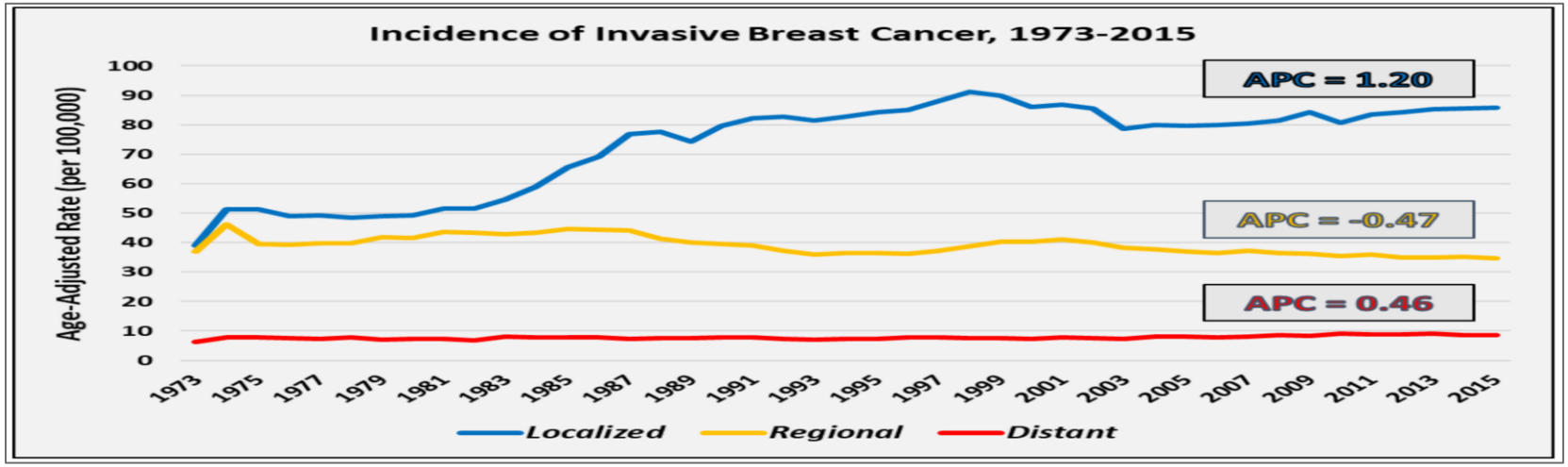
original reports

Early Local Therapy for the Primary Site in De Novo Stage IV Breast Cancer: Results of a Randomized Clinical Trial (EA2108)

Yunfang Yu, MD[1], Huangming Hong, MD[1], Ying Wang, MD[1], Tuping Fu, MD[2], Yongjian Chen, MD[3], Jianli Zhao, MD[1], Peixian Chen, MD[4], Ruizhao Cai, MD[2], Yujie Tan, MD[1], Zifan He, MD[1], Wei Ren, MD[1], Lihuan Zhou, MD[2], Junhao Huang, MD[2], Jun Tang, MD[2], Guolin Ye, MD[4], and Herui Yao, MD[1]

Before Match

After Match



- ✓ Metanalisi di studi prospettici
- ✓ Propensity Score Matching
- ✓ 1110 pazienti
- ✓ 6 Studi

Yu Y, et al: Ann Surg Oncol 2021; 28: 5059-5070

Meta-analisi studi retrospettivi

Breast Cancer Res Treat (2010) 120:9–16
DOI 10.1007/s10549-009-0670-0

REVIEW

Impact of breast surgery on survival in patients with distant metastases at initial presentation: a systematic review of the literature

Jetske Ruiterkamp · Adri C. Voogd · Koop Bosscha · Vivianne C. G. Tjan-Heijnen · Miranda F. Ernst

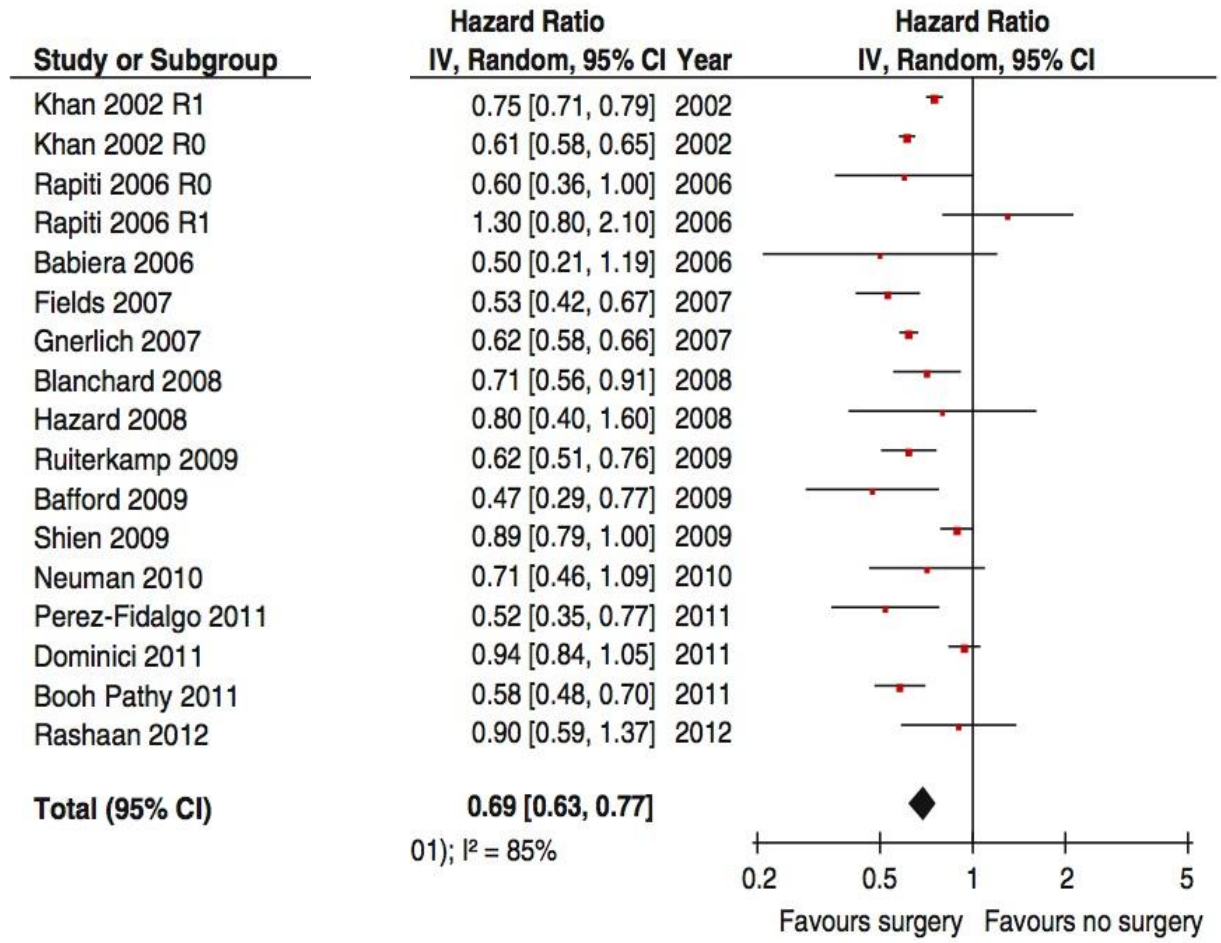
Med Oncol (2012) 29:3282–3290
DOI 10.1007/s12032-012-0310-0

REVIEW ARTICLE

Surgery of primary tumors in stage IV breast cancer: an updated meta-analysis of published studies with meta-regression

Fausto Petrelli · Sandro Barni

Meta-analisi studi retrospettivi



Studi Retrospettivi: Analisi dei Sottogruppi

Age		T1-2 %		ER + %		One organ %		No-Visceral disease %	
Surgery	None	Surgery	None	Surgery	None	Surgery	None	Surgery	None
50*	55	40	43	51	65	82*	68	49**	23
51.4	51.5	56	45	57	64	33**	10	92	66
63.3*	57.1	19 (T1)*	7 (T1)	82*	72	81**	49	35**	63
55.9*	58.9	44**	27	NR	NR	NR	NR	66*	70
62**	66	58**	27	48**	35	NR	NR	NR	NR
52.7*	57.5	21	27	53**	78	72	53	57	66
62.5	62.5	61	NR	NR	NR	60**	35	52.7	NR
61.8**	71.6	39*	25	NR	NR	61*	41	43*	58
60.2*	64.8	60**	37	NR	NR	79**	63	53	60
53 (< 50)*	65 (< 50)	25	22	NR	NR	NR	NR	36**	63
69 (< 50)**	NR	49**	NR	49**	NR	41**	NR	NR	NR
49	50	10	10	41**	27	74	44	32	24
55.9	59.2	12 (T1)	6 (T1)	41	39	69**	46	42*	66
53.4*	56.3	NR	NR	72	71	69*	51	57	64
53	58	NR	NR	70	68	29**	3	52	64

*p=0.05 - 0.001 **p<0.001 NR: not reported

A Prospective Analysis of Surgery in Stage IV Breast Cancer

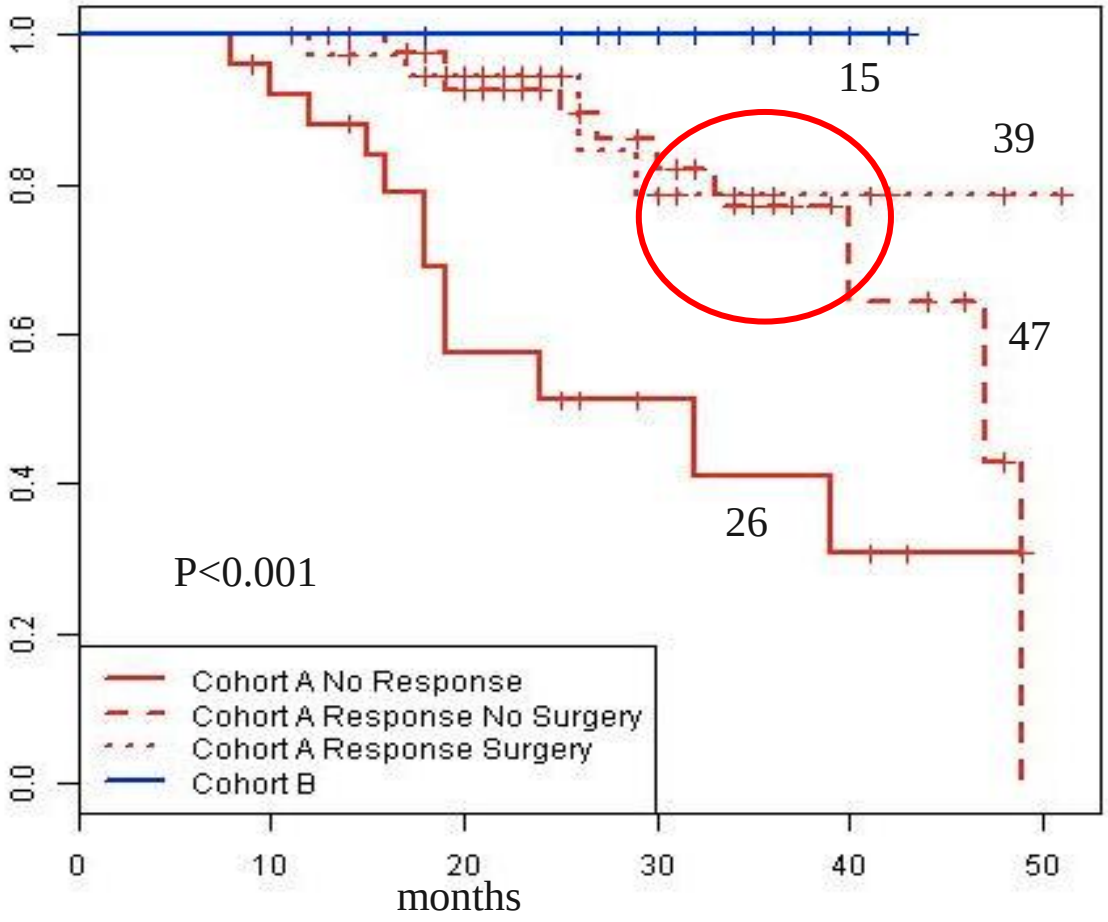
Translational Breast Cancer Research Consortium (TBCRC 0013)

- Prospectively characterize patients presenting with stage IV breast cancer in the modern era while documenting clinical management and outcomes
  - establish a registry for the collection of patient demographics, clinical and pathological data, blood samples and tissue samples.

tbcrc Translational Breast Cancer Research Consortium

King TA et al , San Antonio BCC, 2014 - Poster Session 2, #18-09

TBCRC 013
Multivariate models for OS



Stepwise Cox regression including age, size, ECOG status, HR, Her2, cohort A/B, response and surgery.

	N	2yr OS (95%CI)
Cohort A, NR*	26	51% (33-80%)
Cohort A, R no S**	47	93% (85-100%)
Cohort A, R + S	39	95% (88-100%)
Cohort B	15	100% (76-100%)

*median OS 32mos (19-NR); **median OS 47mos(40-NR)
R = responders, NR= Non-responders, S = surgery

King TA et al Poster Session 2, 18-09

Trials Randomizzati

Country	Accrual Period	N Projected	N Accrual	Initial Therapy	Status
India (Tata Memorial)	2005-12	350	350	Systemic Therapy	Published
Turkey (MF 07-01)	2008-12	271	274	Surgery	Published
Austria (ABCSG 28) (POSYTIVE)	2010-15	254	90	Surgery	Early Stopped
Netherlands (SUBMIT)	2011-16	516	0	Surgery	Early Stopped
Japan JCOG 1017	2011-18	500	400	Systemic Therapy	Completed
USA and Canada ECOG 2108	2011-16	880	368	Systemic Therapy	Completed

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Bias degli studi retrospettivi

- Pazienti giovani
- Migliore accesso alle cure
- Tumori più piccoli (30-40% T1-T2)
- Tumori luminal-like
- Interessamento metastatico "single site"
- Prevalenza di metastasi ossee e tessuti molli

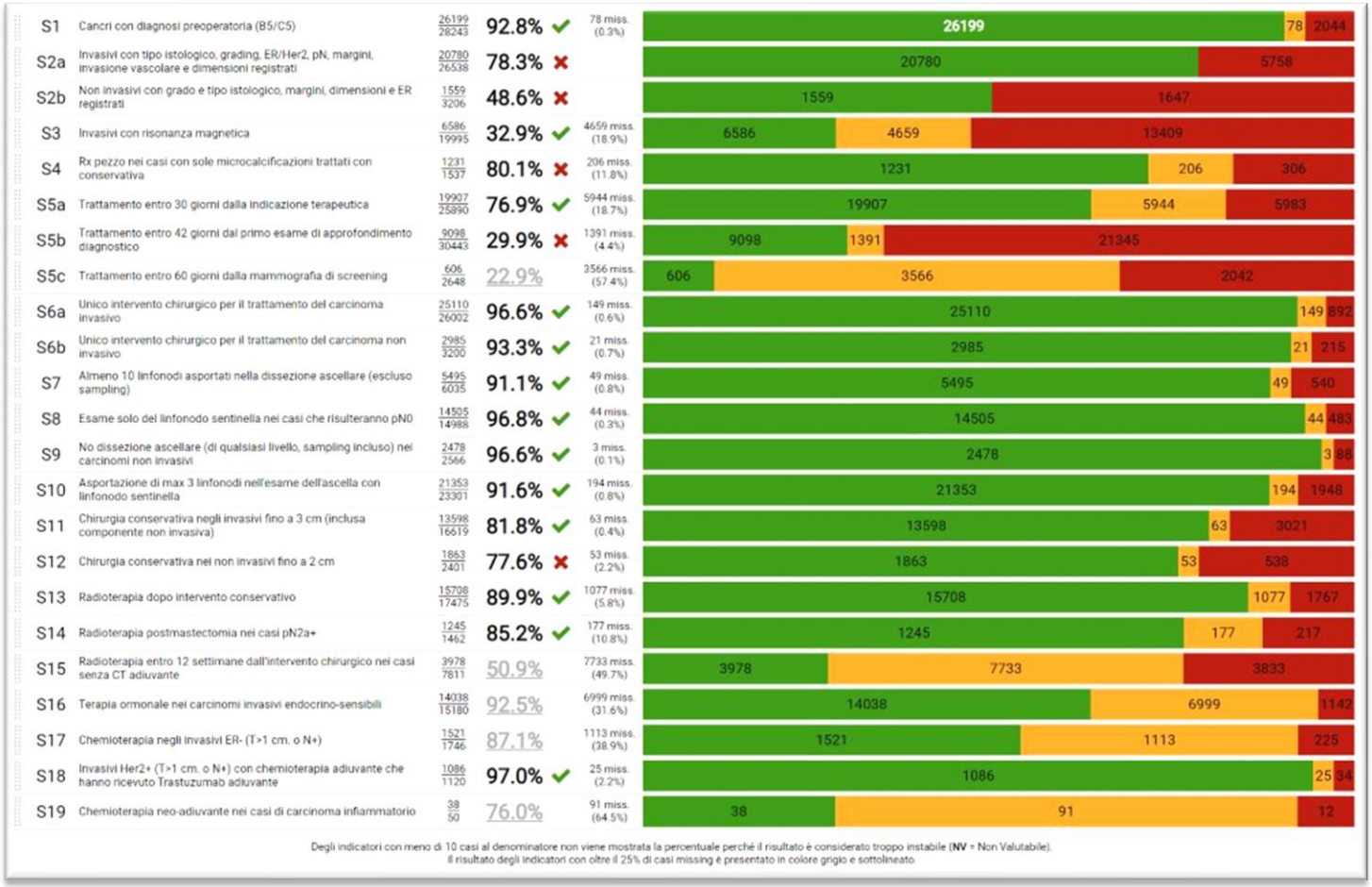
Senonet

senonet

Il software che consente il monitoraggio della qualità della diagnosi, del trattamento e del follow-up del carcinoma mammario nei centri afferenti a Senonetwork.

2017-2021	58531 PAZIENTI	61455 LESIONI	20 CENTRI

Performance dei centri partecipanti in relazione agli Indicatori Senonetwork per gli anni 2017-2019



Certificazione Europea