

MASTECTOMIA PROFILATTICA NELLA PAZIENTE CON CARCINOMA MAMMARIO IN STADIO INIZIALE: QUALI EVIDENZE NEL 2017?

Chiara Boccardo

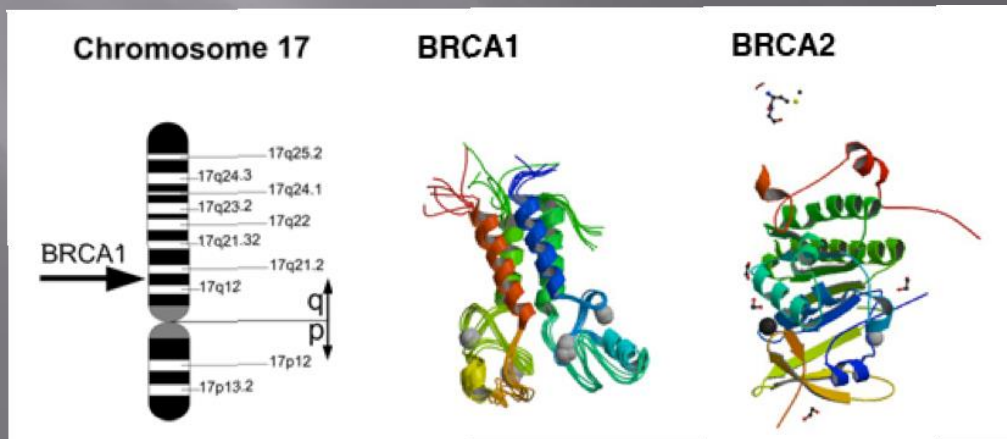
Unità di Senologia
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Negrar



UN PO' DI NUMERI...



- ▣ 40,000-60,000 NUOVI CASI DI TUMORE ALLA MAMMELLA OGNI ANNO IN ITALIA
- ▣ 5%-10% PAZIENTI BRCA1-2 MUTATE
- ▣ 56%-86% RISCHIO DI SVILUPPO TUMORE MAMMARIO NELLE PAZIENTI MUTATE



UN PO' DI NUMERI...



0.5-2.5% RISCHIO DI TUMORE MAMMARIO
CONTROLATERALE IN PAZIENTI NON
MUTATE PER ANNUM



AUMENTO INCIDENZA DI RICHIESTA DI MASTECTOMIA
PROFILATTICA CONTROLATERALE CHE VARIA DALLO
0,26 - 0,45 % PER ANNUM

DAL 1998 AL 2011 INCREMENTO DI MASTECTOMIE
PROFILATTICHE 2% → 24.5%

AND THE WINNER IS...

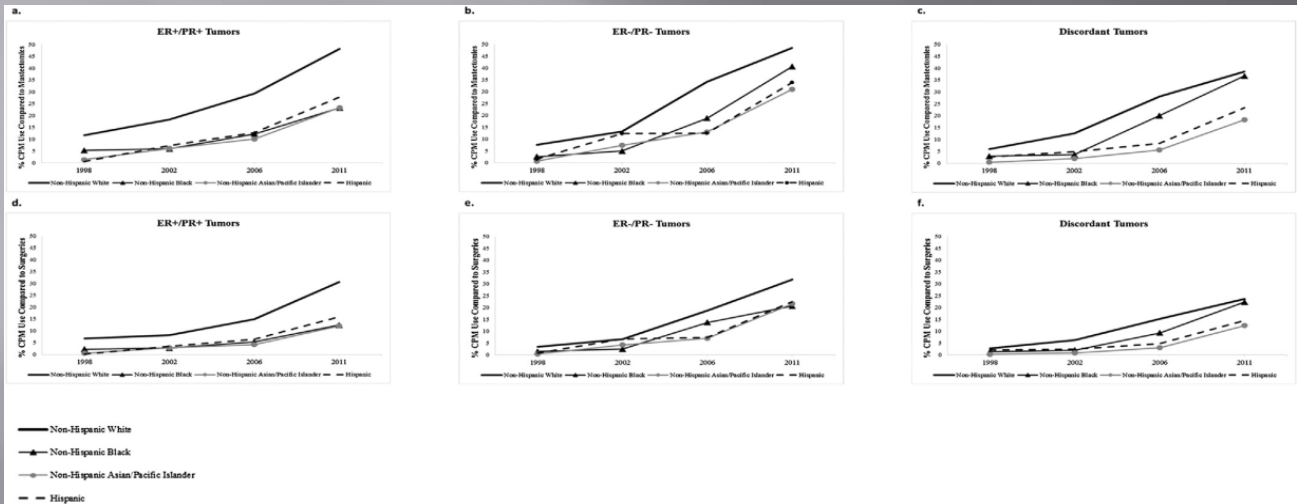


Table 1 Participant characteristics

Diagnosis	
Invasive ductal cancer (n = 31)	27.4%
Invasive cancer (n = 26)	23.0%
Ductal carcinoma in situ (n = 23)	20.4%
Mass/lump (n = 11)	9.7%
Invasive lobular cancer (n = 9)	8.0%
Other (n = 13)	11.5%
Diagnosis dichotomy (n = 113)	
Less serious (n = 47)	41.6%
More serious (n = 66)	58.4%
Income	
Less than 25 K (n = 7)	6.2%
25-50 K (n = 20)	17.7%
51-75 K (n = 25)	22.1%
76-100 K (n = 17)	15.0%
101 K (n = 30)	10.6%
Declined to Answer (n = 14)	12.3%
Income dichotomy (n = 99)	
Less than 51 K (n = 27)	23.9%
51 K + (n = 72)	63.7%
Insurance	
Private (n = 80)	71.4%
Medicare/Medicaid (n = 12)	10.8%
Other (n = 13)	11.5%
Declined to Answer (n = 7)	6.3%
Insurance dichotomy (n = 105)	
Private (n = 80)	76.1%
Other (n = 25)	23.8%
Race/ethnicity	
White (n = 99)	87.6%
Black (n = 12)	10.6%
Hispanic (n = 2)	1.8%
Race/ethnicity dichotomy	
White (n = 99)	87.5%
Minority (n = 14)	12.5%
Marital status	
Married/partnership (n = 86)	76.8%
Divorced/separated (n = 12)	10.7%
Single (n = 8)	7.1%
Widowed (n = 6)	5.4%
Education	
High school or less (n = 22)	19.5%
Some college (n = 36)	32.1%
Bachelor's degree (n = 32)	28.6%
Graduate degree (n = 21)	18.8%

- **AGE:** 35-45 years
- **RACE:** Caucasian – Hispanic – Non hispanic Black – Asian
- **EDUCATION:** Degree – Phd
- High social and economic status

RECIDIVA CONTROLATERALE : RISCHIO REALE O PERCEPITO?



RISCHIO REALE

RESEARCH

Open Access

The Manchester guidelines for contralateral risk-reducing mastectomy



Narendra Nath Basu^{1,4*}, G L Ross², D G Evans^{1,3} and L Barr¹

Table 2 Summary of risk factors for CBC and levels of evidence [8]

Family history—<45 years with a first-degree relative (RR 2.5)—<55 years with first degree relative (RR 1.5)—first degree relative with bilateral disease (RR 3.5) Level II evidence (Reiner AS JCO—2013) [18]

Gene mutation status—BRCA1/2 mutation (RR4) Level II evidence (Metcalfe 2004 JCO; Evans 2013) [4, 25]

Chest radiotherapy for Hodgkin's lymphoma—rate of CBC unknown

Young age at diagnosis—<30 years 0.5–1.3 % annual CBC rate Level II evidence (Nichols, Lacey JCO 2011) [2]

ER status—ER positive (reference point RR 1)—ER negative (RR 1.3) Level II evidence [26]

Anti-endocrine treatment (risk reduction), tamoxifen 50 % Aromatase inhibitor 70 % Level I evidence [27, 28]

DCIS—0.6 % annual CBC risk of DCIS and/or invasive carcinoma (RR 1.0) Level I evidence [21]

Lobular histology combined with family history (RR2.0)

Oophorectomy under 40 years (risk reduction) (RR0.5)

Early menopause <45 year (risk-reduction)—published as abstract [29]

RISCHIO PERCEPITO

Table 2 Mean comparisons of participant demographics among CPM motivations

	Patient Dichotomized Demographics											
	Diagnosis		Age		Education		Employment		Income		Insurance	
	Less	More	Low	High	Low	High	No	Yes	Low	High	Public	Private
CPM Motivations												
Avoiding Treatment	1.79 (1.15)	2.40 (1.30)**	1.76 (1.21)	2.38 (1.26)**	2.26 (1.26)	1.96 (1.21)	2.45 (1.32)	1.97 (1.18) [†]	2.46 (1.45)	2.08 (1.14)	1.81 (1.34)	2.16 (1.22)
Reducing Long-term Risk	4.38 (.91)	4.06 (.89) [†]	4.31 (.84)	4.11 (.95)	4.19 (.91)	4.18 (.93)	3.99 (.87)	4.29 (.93)	4.52 (.67)	4.03 (.98)**	4.15 (.94)	4.27 (.89)
Avoiding Future Visits	2.09 (1.36)	2.35 (1.14)	2.25 (1.30)	2.23 (1.21)	2.23 (1.10)	2.19 (1.35)	2.47 (1.09)	2.09 (1.27)	2.39 (1.09)	2.25 (1.27)	1.96 (1.15)	2.23 (1.26)
Symmetry	3.42 (1.53)	3.42 (1.39)	3.82 (1.42)	3.16 (1.41)*	3.05 (1.45)	3.77 (1.37)**	3.11 (1.37)	3.58 (1.45)	3.54 (1.70)	3.56 (1.27)	3.29 (1.71)	3.48 (1.41)

QUALE TECNICA?



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**MASTECTOMIA
CONTROLATERALE:
UN REALE
BENEFICIO?....**

Table 2 Single- and multi-institution studies examining disease-free and overall survival in patients undergoing CPM

Study	Year published	No of CPM patients	Data source	DFS/DSS (adjusted)	OS (adjusted)	Follow-up
Peralta et al ³²	2000	64	Retrospective, single institution	DFS: 71% CPM vs 53% control ($P=0.06$)	64% CPM vs 48% control ($P=0.26$)	Mean: 6.8 years
Herrinton et al ³³	2005	1,072	Cancer Research Network, Kaiser Permanente	DSS: HR =0.57 (95% CI, 0.45–0.72)	All-cause mortality: HR =0.60 (95% CI, 0.50–0.72)	Median: 5.7 years
Bedrosian et al ³⁴	2010	8,900	SEER	DSS: HR =0.63 (95% CI, 0.57–0.69)	NA	Median: 47 months
Brewster et al ³⁵	2012	532	Retrospective, single institution	DFS: HR =0.75 (95% CI, 0.59–0.97)	OS: HR =0.74 (95% CI, 0.56–0.99)	Median: 4.5 years
Boughey et al ³⁹	2010	385	Retrospective, single institution	DFS: HR =0.67 (95% CI, 0.54–0.84)	OS: HR =0.77 (95% CI, 0.60–0.98)	Median: 17.3 years
Chung et al ³⁶	2012	177	Retrospective, single institution	No difference in DFS between UM and bilateral mastectomy ($P=0.081$)	No difference in OS between UM and bilateral mastectomy ($P=0.42$)	Median: 61 months
Yao et al ³⁷	2013	14,994	NCDB	NA	OS: HR =0.88 (95% CI, 0.83–0.93)	Median: 5 years
Kruper et al ³⁸	2014	26,526	SEER	DSS: HR =0.83 (95% CI, 0.77–0.90)	OS: HR =0.77 (95% CI, 0.73–0.82)	NA
Kurian et al ¹⁹	2014	11,692	California Cancer Registry	NA	OS: HR =1.02 (95% CI, 0.94–1.11)	Median: 89.1 months



- RISULTATI CONTROVERSI
- NO STUDI PROSPETTICI RANDOMIZZATI
- SELECTION BIAS

Contralateral Prophylactic Mastectomy (CPM) Consensus Statement from the American Society of Breast Surgeons: Data on CPM Outcomes and Risks

Judy C. Boughey, MD¹, Deanna J. Attai, MD², Steven L. Chen, MD, MBA³, Hiram S. Cody, MD⁴, Jill R. Dietz, MD⁵, Sheldon M. Feldman, MD⁶, Caprice C. Greenberg, MD, MPH⁷, Rena B. Kass, MD⁸, Jeffrey Landercasper, MD⁹, Valerie Lemaine, MD, MPH¹, Fiona MacNeill, MB, BS¹⁰, David H. Song, MD¹¹, Alicia C. Staley, BS, MBA, MS¹², Lee G. Wilke, MD⁷, Shawna C. Willey, MD¹³, Katharine A. Yao, MD¹⁴, and Julie A. Margenthaler, MD¹⁵

Summary Risk of CBC for average-risk women with breast cancer is 0.1 to 0.6 % per year. CBC risk is higher for women diagnosed at a young age, those with a strong family history, and *BRCA* carriers.

There is strong evidence that CPM reduces the relative risk of cancer in the contralateral breast by 90 to 95 %; however, breast cancer risk is not completely eliminated with CPM. The absolute risk of developing cancer on that side after CPM ranges from 0 to 1.5 %.^{20–25}

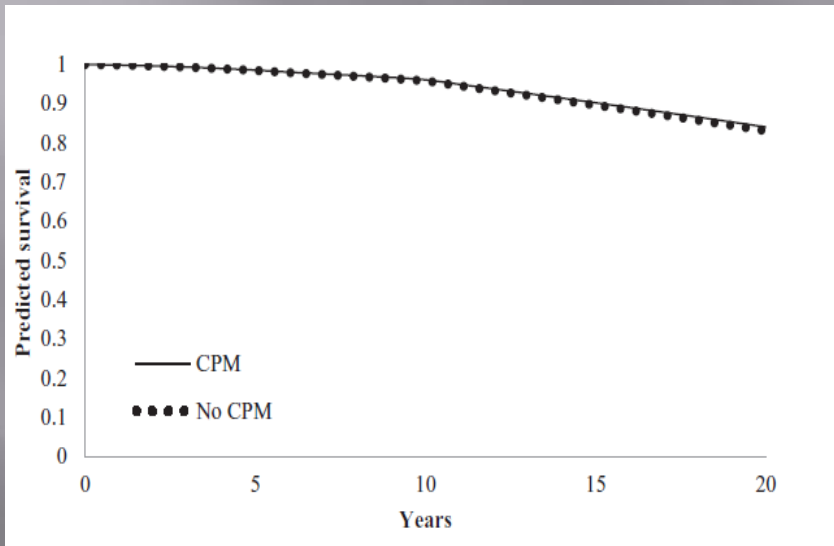
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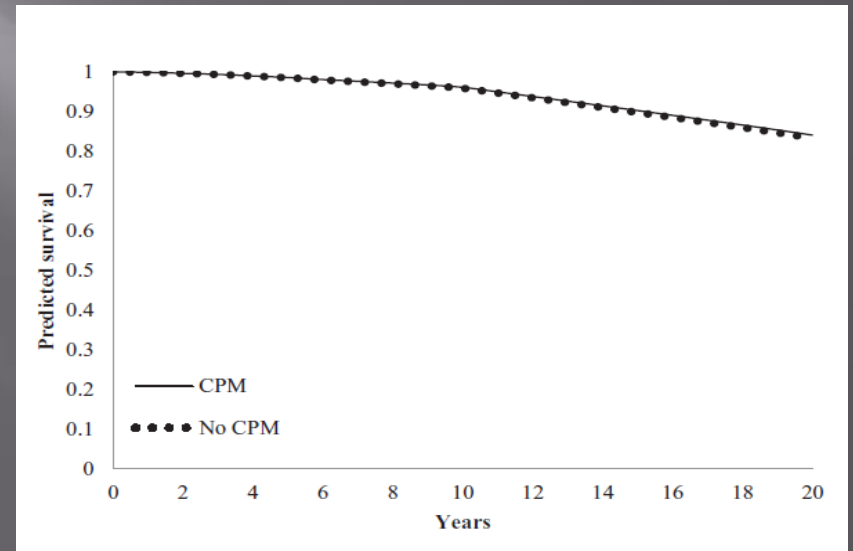
Summary CPM does not appear to be associated with a survival benefit, with the possible exception of *BRCA* carriers.

Survival Outcomes After Contralateral Prophylactic Mastectomy: A Decision Analysis

Pamela R. Portschy, Karen M. Kuntz, Todd M. Tuttle



ER/PR+



ER/PR-

.... O SOLO UN AZZARDO??

- ▣ MAGGIORE TEMPO DI ANESTESIA (2-6 H)
- ▣ MAGGIORE OSPEDALIZZAZIONE (2-11 GG)
- ▣ MAGGIOR TASSO DI COMPLICANZE POST OPERATORIE
- ▣ MAGGIORI COSTI

Table 1

Complications of mastectomy.

Seroma formations (25–60%)

Wound infections (2.8–15%)

Skin flap necrosis (1–22%)

Hematoma (2%)

Complications of implants

Prosthesis infection (0.5–2%)

**Capsular contraction (3–5% up to 30%
depending on type of implants)**

Device failure and rupture (10%)

Complications of autologous tissue reconstruction

Flap necrosis (1–3%)

Wound infection (4–8%)

Functional impairment (variable)

Abdominal hernias (20%)



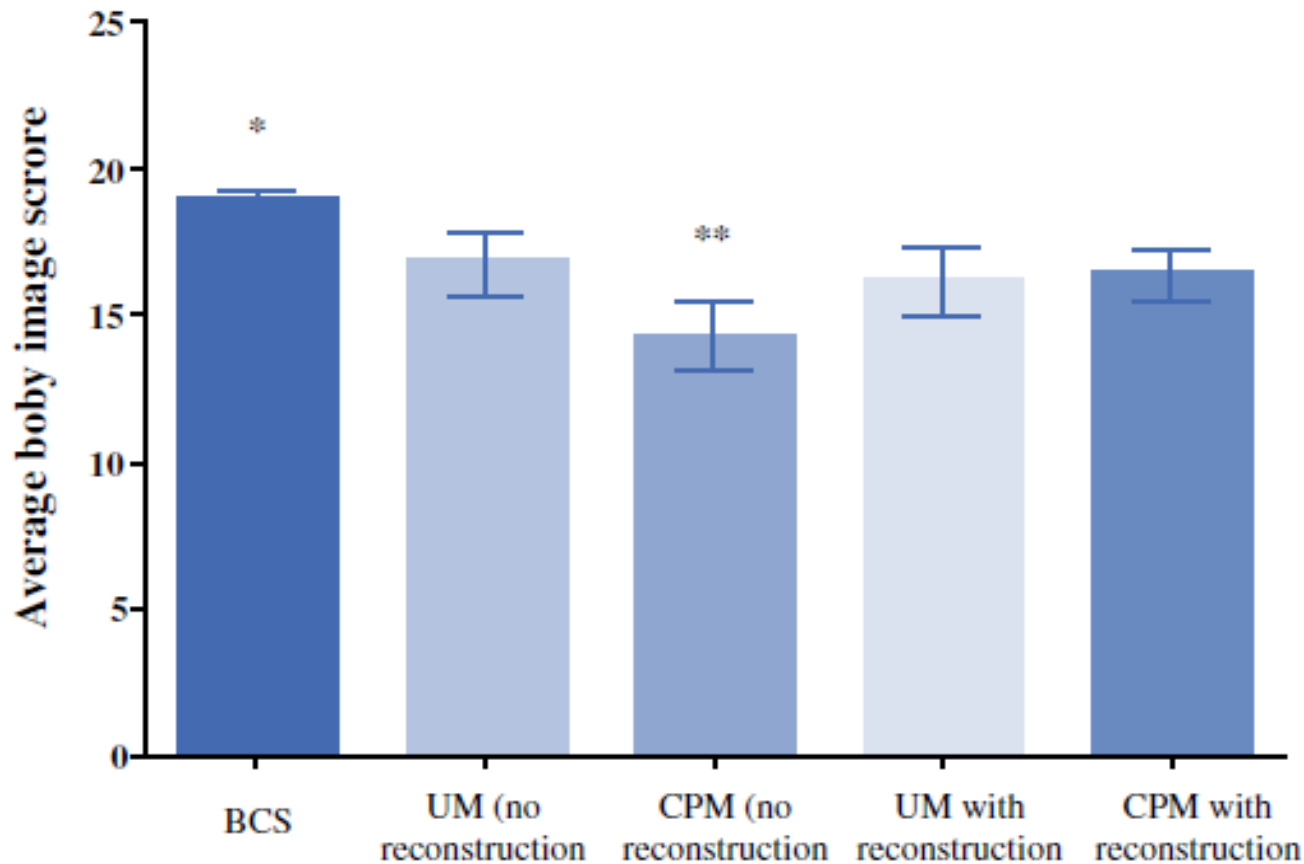
Figure 3 - Infection on the topography of a breast reconstructed using a permanent expander. The patient developed worsening of symptoms, requiring the removal of the expander.



PATIENTS SATISFACTION?

Long-Term Satisfaction and Body Image After Contralateral Prophylactic Mastectomy

Chelsea Anderson, MPH¹, Jessica Y. Islam, MPH¹, M. Elizabeth Hodgson, PhD², Susan A. Sabatino, PhD³, Juan L. Rodriguez, MPH, MS³, Clara N. Lee, MD, MPP⁴, Dale P. Sandler, PhD⁵, and Hazel B. Nichols, PhD¹



TAKE HOME MESSAGES

CPM should be considered for those at significant risk of CBC

- Documented *BRCA1/2* carrier.
- Strong family history, but patient has not undergone genetic testing.
- History of mantle chest radiation before age 30 years.

CPM can be considered for those at lower risk of CBC

- Gene carrier of non-*BRCA* gene (e.g., *CHEK-2*, *PALB2*, *p53*, *CDH1*).
- Strong family history, patient *BRCA* negative, no known *BRCA* family member.

CPM may be considered for other reasons

- To limit contralateral breast surveillance (dense breasts, failed surveillance, recall fatigue).
- To improve reconstructed breast symmetry.
- To manage risk aversion.
- To manage extreme anxiety. (This may be better managed through psychological support strategies.)

TAKE HOME MESSAGES

CPM should be discouraged

- Average-risk woman with unilateral breast cancer.
- Women with advanced index cancer (e.g., inflammatory breast cancer, T4 or N3 disease, stage IV disease).
- Women at high risk for surgical complications (e.g., patients with comorbidities: obesity, smoker, diabetes).

GUIDELINES



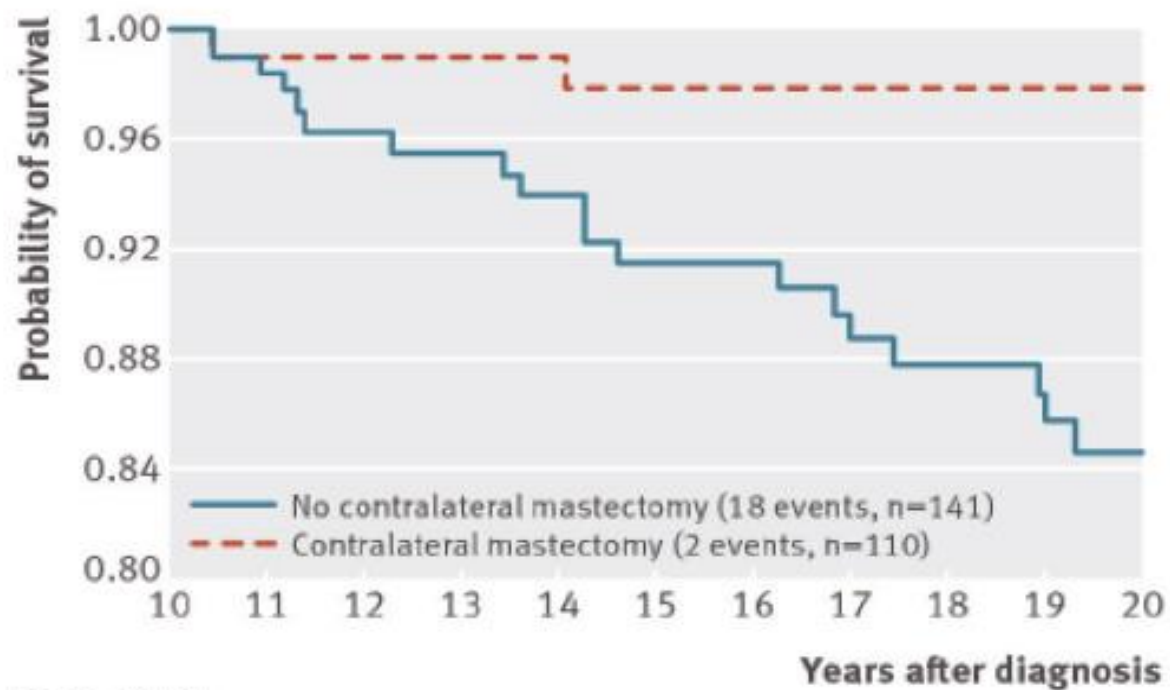
GRAZIE PER L'ATTENZIONE



Risk-Reducing Mastectomy (RRM) and Risk of First Breast Cancer (BC) *

	Prior or concurrent RRSO			No prior or concurrent RRSO		
	ALL	<i>BRCA1</i>	<i>BRCA2</i>	ALL	<i>BRCA1</i>	<i>BRCA2</i>
Total Participants	959	617	342	660	415	245
Total RRM ("Exposed")	172	116	56	75	43	32
Post-RRM BC	0	0	0	0	0	0
Total non-RRM ("Controls")	787	501	286	585	372	213
Controls with BC	64 (8%)	44 (9%)	20 (7%)	34 (6%)	19 (5%)	15 (7%)
Mean Age at RRM	40.7 (22.4-64.6)	40.1 (24.8-62.5)	42.0 (22.4-64.6)	37.9 (22.4-64.6)	36.7 (24.8-52.1)	39.4 (22.4-64.6)
Mean Age Start of Follow-Up	40.5 (18.3-87.8)	39.5 (18.3-87.8)	42.2 (18.9-79.7)	37.6 (18.3-87.8)	36.7 (18.3-87.8)	39.1 (18.9-79.7)
Mean Yrs Follow-up to BC (Range)	3.1 (0.5-9.3)	3.3 (0.5-9.3)	2.6 (0.6-6.8)	3.1 (0.6-8.71)	3.6 (0.6-8.7)	2.5 (0.6-6.8)
Mean Yrs Follow-up to Censor (Range)	3.5 (0.5-13.0)	3.7 (0.5-13.0)	3.0 (0.5-11.5)	2.7 (0.5-13.0)	2.7 (0.5-13.0)	2.5 (0.5-11.5)
Occult BC ***	4	3	1	3	2	1
HR **** (95% CI); N	No cancer events	No cancer events	No cancer events	No cancer events	No cancer events	No cancer events

* No breast cancer prior to ascertainment or RRSO, participants censored at OC, death or date of last contact.



•La mastectomia controlaterale è associata ad una riduzione del rischio di decesso per carcinoma mammario del 48%

No in study

Contralateral mastectomy

110 104 95 92 83 71 61 58 45 42 39

No contralateral mastectomy

141 134 127 122 116 108 101 94 87 83 72

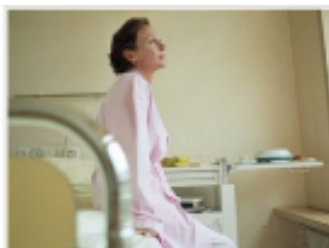
Double Mastectomy Procedures: Study Finds No Benefit to Most Patients

June 26, 2014 at 4:55 pm

When a woman has been diagnosed with breast cancer, one of the most common options of treatment is a mastectomy. An increasing number of women are choosing to have double mastectomies, even when the cancer only appears in one breast. But a [new study](#), conducted by the University of Michigan Comprehensive Cancer Center, concluded in most cases a double mastectomy is [unnecessary](#).

Researchers followed the cases of 3,447 women who were diagnosed and treated for cancer in one breast and had not had cancer show up in the other breast. Eight percent of the women in the group had opted for a double mastectomy – medically referred to as a contralateral prophylactic mastectomy (CPM). The data showed that women with higher education levels, as well as women who had undergone an MRI prior to treatment, were more likely to choose a CPM.

Seventy percent of the women who chose to have a CPM did not have a strong family history of breast or ovarian cancer. They also did not test positive for mutated BRCA genes. A positive test to mutated BRCA genes indicates a strong likelihood of breast (and ovarian cancer). It is medically recommended that women who test positive undergo CPM.



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\$ _____ - MEDICAL MALPRACTICE - SURGERY - ALLEGED MALPRACTICE BY SURGEON WHO RECOMMENDED PLAINTIFF HAVE PROPHYLACTIC BILATERAL MASTECTOMY AND ALLEGED MALPRACTICE BY SECOND SURGEON WHO SUPPORTED RECOMMENDATION.



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Mastectomy Malpractice

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Mon, Jul 29 2013 1:41 AM

texasberry
Consumer



Joined on Mon, Jul 29 2013
TX
Posts 2

Mastectomy Malpractice

[Reply](#)

In May 2012 I chose to undergo a preventive double mastectomy after finding out I had the bra mutation. I chose to do immediate reconstruction and chose the 'nipple sparing' technique. I was told I would only have 1 surgery. A week after my mastectomy and reconstruction I had a post op appt and was told I needed surgery the next morning because my skin was not surviving and they needed to remove my nipples. The only reason I chose this particular surgeon was because they did the nipple sparing technique. Now I went in for the surgery they removed the part the wasn't surviving but the surgeries were not complete. I was emotionally distraught, I am only 27 years old and I chose to do one technique and was told I only needed one surgery and I was on my second surgery with no nipples. I go in for my third surgery to replace my implants and do 'scar revision' which made my scars even bigger! I now have scars from my arm pit all the way across to my other arm pit with a one inch gap in the middle. My scars are bright red and raised, they hurt, they are itchy, and I don't look normal. I go back to the surgeon for them to do 'fat grafting' which they said would give my breasts a more natural look. So by now I am on my fourth surgery which was only supposed to be one, and the fat grafting did nothing for them except leave more scars. I still haven't had nipple reconstruction done and they do not look the way they are. I am now 28 and am going thru a very hard time emotionally and physically. I look at pictures from other surgeons and I have not seen anyone with the type and scarring I have. I still have a couple more surgeries to go to get this corrected so I am wondering if this sounds like I may have a malpractice suit? Any kind of feedback will be

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DOWNEY v. DUNNINGTON SIU

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Appellate Court of Illinois, Fourth District.

Sandra G. DOWNEY, n/k/a Sandra G. Hart, Plaintiff-Appellant, v. Gary DUNNINGTON, M.D., and SIU Physicians and Surgeons, Inc., Defendants



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