SURGICAL MANAGEMENT OF DUCTAL CARCINOMA IN SITU

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FINANCIAL DISCLOSURE

- Susan G. Komen for the Cure®
- European School of Oncology (ESO)
- Pan American Health Organization (PAHO)
- Sheikh Mohammed Hussein Al-Amoudi Center of Excellence in Breast Cancer
- American Society of Clinical Oncology (ASCO)
- Navidea Biopharmaceuticals
- GE Healthcare
- Sanofi-Aventis

DUCTAL CARCINOMA IN SITU Outline

Diagnosis and extent of disease evaluation
Breast conservation vs. mastectomy
Surgical margins and nipple-sparing
Adjuvant radiation and endocrine therapy

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SCREENING MAMMOGRAM: Cranio-Caudal (CC) View



U.S. FEMALE CANCER INCIDENCE RATES, 1973-2005



U.S. AGE-ADJUSTED BREAST CANCER, 1973-1997



U.S. FEMALE CANCER DEATH RATES, 1930-2005



DIAGNOSTIC MAMMOGRAM:



CORE NEEDLE BIOPSY:









IN SITU BREAST CANCER DCIS with Comedo Necrosis





Vacuum Assisted Biopsy System



NCCN Guidelines Version 1.2012 Breast Cancer

DIAGNOSIS

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PRIMARY TREATMENT



SEGMENTAL BREAST ANATOMY

Ductal tree follows segmental distribution

Breast cancers often follow anatomy of ductal tree

 Collateral circulation permits lumpectomy without necrosis



SEGMENTAL BREAST ANATOMY

- Going and Moffat, 2002 University of Glasgow
- 2mm serial sections of autopsied breast
- 3-D computer model reconstruction
- Segmental ductal anatomy observed



SEGMENTAL BREAST ANATOMY

- Sir Astley Cooper (1768-1841)
- Gross autopsy breast specimens
- Wax / mercury ductal injections
- Segmental ductal anatomy observed



CANCER DISTRIBUTION PATTERNS

BREAST CANCER PATTERNS: Disease Distribution Categories

Localized

Segmentally Extended

Irregularly Extended

BREAST CANCER PATTERNS: Localized





BREAST CANCER PATTERNS: Segmentally Extended



BREAST CANCER PATTERNS: Irregularly Extended



BREAST CANCER PATTERNS: Partial Mastectomy Selection Localized - lumpectomy Segmentally Extended - oncoplastic

Irregularly Extended – mastectomy

MRI FOR EXTENT OF DISEASE: Additional Biopsies

111 consecutive women with 121 cancerous breasts
Median age 48.7yrs; 50% had palpable disease
Mammographic sensitivity 100% in fatty breasts

Biopsy before definitive surgery

- MRI: 145 additional biopsies: 66 were benign; 12 were atypical
- Mammography: 43 biopsies: 20 were benign; 6 were atypical
- Ultrasound: 93 biopsies: 42 were benign; 6 were atypical

Berg, et al., Radiology 233:830,2004

MRI FOR EXTENT OF DISEASE: Impact on Surgical Management

<u>8.1%</u> (95% CI, 5.9–11.3) of all women eligible for breast-conserving surgery were treated with mastectomy because of MRI-only detection of additional disease

Additional <u>5.5%</u> (95% CI, 3.1–9.5) of women had more extensive surgery (wider excision or mastectomy) because of false-positive findings on MRI including 1.1% (95% CI, 0.3–3.6) who converted to mastectomy

Houssami and Hayes, CA Cancer J Clin 59:290, 2009

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MODIFIED RADICAL MASTECTOMY



RADICAL MASTECTOMY



EVOLUTION IN CANCER TREATMENT



BREAST CONSERVING SURGERY



BREAST CONSERVING RADIATION THERAPY



BREAST CONSERVATION: Long-term validation

The New England Journal of Medicine

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TWENTY-YEAR FOLLOW-UP OF A RANDOMIZED TRIAL COMPARING TOTAL MASTECTOMY, LUMPECTOMY, AND LUMPECTOMY PLUS IRRADIATION FOR THE TREATMENT OF INVASIVE BREAST CANCER

BERNARD FISHER, M.D., STEWART ANDERSON, PH.D., JOHN BRYANT, PH.D., RICHARD G. MARGOLESE, M.D., MELVIN DEUTSCH, M.D., EDWIN R. FISHER, M.D., JONG-HYEON JEONG, PH.D., AND NORMAN WOLMARK, M.D.

TWENTY-YEAR FOLLOW-UP OF A RANDOMIZED STUDY COMPARING BREAST-CONSERVING SURGERY WITH RADICAL MASTECTOMY FOR EARLY BREAST CANCER

UMBERTO VERONESI, M.D., NATALE CASCINELLI, M.D., LUIGI MARIANI, M.D., MARCO GRECO, M.D., ROBERTO SACCOZZI, M.D., ALBERTO LUINI, M.D., MARISEL AGUILAR, M.D., AND ETTORE MARUBINI, PH.D.

NSABP B-06:

Effect of Lumpectomy v. Mastectomy on Recurrence


NSABP B-06:

Effect of Lumpectomy v. Mastectomy on Survival



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PRIMARY TREATMENT



AXILLARY NODE DISSECTION: Complication Rates

• Lymphedema

- Acute: 40%

- Chronic: 15-20%

Paraesthesia: 40%

Need for a drain: 100%

• Seroma formation: 10%







SURGICAL AXILLARY STAGING - STAGE I, IIA, IIB and IIIA T3, N1, M0

Clinical Stage I/II



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PRIMARY TREATMENT

Ductal carcinoma in situ (DCIS) Stage 0 Tis, N0, M0 ^a	l	 History and physical exam Diagnostic bilateral mammogram 		Lumpectomy without lymph node surgery + whole breast radiation therapy (category 1)		
		 Pathology review Determination of tumor estrogen receptor (ER) status Genetic counseling if patient is high risk for hereditary breast cancer 	-	or Total mastectomy with or without sentinel node biopsy ± reconstruction or Lumpectomy without lymph node surgery without radiation therapy (category 2B)		

BREAST CONSERVATION Known Distribution of Disease

- 241 mastectomy specimens dissected
- Correlated pathologicradiologic mapping
- Residual carcinoma 2cm from edge of primary tumor found in
 - 29% without EIC
 - 59% with EIC



Holland et al, JCO 8:113, 1990

BREAST CONSERVATION Known Distribution of Disease

Table 1. Probability of Finding Cancer Remaining in the Breast After Simulated Local Excision Related to the Distance From the Edge of the Primary Tumor Exclusive of LCIS

	201-01		Distance From Edge	of Primary Tumor	A		
Any residual carcinoma*	> 0.5 cm		> 2 cm	> 4 cm	> 6 cm	> 8 cm	
	EIC +	74%	59%	32%	21%	9%	
	EIC -	42%	29%	12%	8%	3%	
	P =	.00001	.00004	.0009	.01	.09	
Invasive carcinoma	EIC +	36%	20%	12%	2%	2%	
	EIC —	19%	12%	7%	4%	1%	
	Ρ=	.006	.14	.19	.68	.52	
Intralymphatic carcinoma	EIC +	18%	11%	3%	2%	2%	
	EIC -	11%	7%	4%	3%	1%	
	P	10	12	1.0	47	1.0	
Intraductal carcinoma	EIC +	71%	58%	32%	21%	8%	
	EIC -	28%	19%	5%	4%	1%	
	Ρ=	< .00001	< .00001	< .00001	.0001	.03	

Abbreviation: LCIS, lobular carcinoma in situ.

Holland et al, JCO 8:113, 1990

SURGICAL MARGINS: DCIS – Residual Disease



Initial Excision Margin

Neuschatz, Cady et al, Cancer 94:1917, 2002



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MARGIN STATUS IN DCIS

Substantial controversy exists regarding the definition of a negative pathologic margin in DCIS. Controversy arises out of the heterogeneity of the disease, difficulties in distinguishing the spectrum of hyperplastic conditions, anatomic considerations of the location of the margin, and inadequate prospective data on prognostic factors in DCIS.

Margins greater than 10 mm are widely accepted as negative (but may be excessive and may lead to a less optimal cosmetic outcome).

Margins less than 1 mm are considered inadequate.

With pathologic margins between 1-10 mm, wider margins are generally associated with lower local recurrence rates. However, close surgical margins (<1 mm) at the fibroglandular boundary of the breast (chest wall or skin) do not mandate surgical reexcision but can be an indication for higher boost dose radiation to the involved lumpectomy site (category 2B).



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MARGIN STATUS IN DCIS

- Margins greater than 10 mm are negative
- Margins less than 1 mm are considered inadequate.
- With pathologic margins between 1-10 mm, wider margins are generally associated with lower local recurrence rates.

Skin-Sparing Mastectomy



Skin-Sparing Mastectomy

Introduced in 1991: Toth & Lappert Preserve skin envelope Reconstruction options: **Expander/implant** Tissue: **DIEP/TRAM** Latissimus flap Equivalent cancer outcome Only 36% satisfied with nipple reconstructions



Slide Credit: K. Calhoun

Nipple-Sparing Mastectomy





Nipple-Sparing Mastectomy

 Introduced in 2003: Gerber
 Preserves native nipple
 First used for risk reduction (prophylactic) mastectomies
 Nipple recurrence rare

Only 1 reported NAC cancer recurrence with prophylactic mastectomy



Nipple-Sparing Mastectomy

Introduced in 2003: Gerber **Preserves native nipple USE WITH CANCER?** Nipple involvement **Patient selection** Local recurrence risk



Slide Credit: K. Calhoun

Nipple-Sparing Mastectomy Patient Selection

- T0 or T1/T2 (< 4.5 cm)</p> Peripheral location **Distance from NAC:** Total NAC: 1-2 cm Nipple center: 4 cm Exclusions Paget's **Bloody nipple discharge**
 - Skin retraction



Slide Credit: K. Calhoun

Nipple-Sparing Mastectomy Nipple-Areolar Complex (NAC) Involvement

Study	Year	Number Patients	NAC involvement
Sookhan et al.	2008	18	0%
Voltura et al.	2008	36	5.9%
Petit et al.	2009	1001	5.8%
Jensen et al.	2011	99	14%
Filho et al.	2011	156	3.1%
Boneti et al.	2011	293	2.5%
Spear	2011	49	10%
		Slic	le Credit: K. Calhou

Nipple-Sparing Mastectomy Tumor to NAC Distance

Study	Year	Number Patients	Average Distance	
Sookhan et al.	2008	18	4.8 cm	
Voltura et al.	2008	36	4.9 cm	
Petit et al.	2009	1001	> 1 cm	
Gerber et al.	2009	246	2 cm	
Filho et al.	2011	156	>1 cm	
		_Slid	e Credit: K. Calbour	

Nipple-Sparing Mastectomy Nipple Margin Analysis

Mandatory margin measurement:

- Separate core of nipple base
- Sharp dissection to avoid trauma

Intraoperative assessment

- Frozen section
- Nipple removed if positive
- False negative rates 1-3%

Postoperative assessment

- No false positives or negatives
- Requires reoperation if positive

Nipple-Sparing Mastectomy Local Recurrence Data

Study and Year	Patients	Total Recurrence	NAC specific
Sookhan et al., 2008	18	0%	0%
Voltura et al., 2008	36	5.9%	0%
Gerber et al., 2009	246	10.4%	2.1% (n=1)
Petit et al., 2009	1001	1.4%	0%
Jensen et al., 2011	99	0%	0%
Filho et al., 2011	156	0%	0%
Boneti et al., 2011	293	4.6%	0%
Spear et al., 2011	49	0%	0%

Slide Credit: K. Calhoun

Nipple-Sparing Mastectomy Surgical Approaches



Nipple-Sparing Mastectomy Nipple Viability

Study and Year	Patient s	Nipple necrosis	Incision
Sookhan et al., 2008	18	10%	Areolar/IMF
Petit et al., 2009	1001	5.5%- partial 3.5%- full	N/S
Jensen et al., 2011	99	6.3%	Lateral
Filho et al., 2011	156	0.2%	Lateral/periareolar
Boneti et al., 2011	293	2.1%	IMF
Spear et al., 2011	49	1.8%	Periareolar with lateral extension

Slide Credit: K. Calhoun

Nipple-Sparing Mastectomy Nipple Viability



NIPPLE SPARING MASTECTOMY: University of Arkansas, 2011 • Retrospective Review 1998-2010 – 293 patients underwent 508 procedures: - 281 TSSMs (nipple sparing) / 227 SSMs – 215 bilat operations / 78 unilat operations • Comparable complication rates: - TSSM 7.1% [20 of 281] - SSM 6.2% [14 of 227] (p=0.67)

NIPPLE SPARING MASTECTOMY: University of Arkansas, 2011 • Retrospective Review 1998-2010 – 293 patients underwent 508 procedures: - 281 TSSMs (nipple sparing) / 227 SSMs - 215 bilat operations / 78 unilat operations Comparable locoregional recurrence rates: - TSSM 6% [7 of 152] -SSM 5.0% [7 of 141] (p = 0.89)

NIPPLE SPARING MASTECTOMY: University of Arkansas, 2011 • Retrospective Review 1998-2010 – 293 patients underwent 508 procedures: - 281 TSSMs (nipple sparing) / 227 SSMs – 215 bilat operations / 78 unilat operations Superior cosmesis with TSSM: - TSSM score 9.2 + 1.1 -SSM score 8.3 + 1.9 (p=0.04)

NIPPLE SPARING MASTECTOMY: University of Arkansas, 2011 • Retrospective Review 1998-2010 – 293 patients underwent 508 procedures: - 281 TSSMs (nipple sparing) / 227 SSMs – 215 bilat operations / 78 unilat operations • AUTHORS' CONCLUSION:

 TSSM appears to be oncologically safe with superior cosmesis and can be offered to patients with stages I and II breast cancer

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PRIMARY TREATMENT

Ductal carcinoma in situ (DCIS) Stage 0 Tis, N0, M0 ^a	l	 History and physical exam Diagnostic bilateral mammogram 		Lumpectomy without lymph node surgery + whole breast radiation therapy (category 1)		
		 Pathology review Determination of tumor estrogen receptor (ER) status Genetic counseling if patient is high risk for hereditary breast cancer 	-	or Total mastectomy with or without sentinel node biopsy ± reconstruction or Lumpectomy without lymph node surgery without radiation therapy (category 2B)		•

BREAST CONSERVATION: Radiation Therapy Concepts

- Surgical lumpectomy: removes tumor bulk
- Radiation therapy after surgery: eradicates residual microscopic cancer
- POSTOPERATIVE RADIATION TREATMENT DECREASES LOCAL
 RECURRENCE RISK OF BREAST
 CANCER FROM 30-40% to 10%

LOCAL RECURRENCE WITH BCT



Huston and Simmons, Amer J Surg 189:229, 2005
SURGICAL MARGINS: DCIS in NSAPB B-17

Table 3. Distribution by Pathologic Characteristics of DCIS and Hazard Rates of IBT According to Treatment

		Lumpectomy + irradiation				
Characteristic	No. at risk N = 274	No. IBT N = 38	Hazard rate/100	No. at risk N = 299	No. IBT N = 15	Hazard rate/100
Nuclear grade						
Poor	128	22	5.62	147	10	2.09
Good	146	16	3.08	152	5	0.90
Comedo necrosis						
Moderate/marked	123	24	6.48	131	7	1.63
Absent/slight	151	14	2.59	168	8	1.32
Unknown	15	2	5.49	17	1	1.97
Pathologic tumor size						
<1.0 cm	236	32	4.11	263	14	1.54
≥1.0 cm	32	6	4.70	31	1	0.96
Unknown	2	0	0	5	0	0
Lumpectomy margins						
Free	223	25	3.33	249	10	1.18
Uncertain/involved	51	13	8.09	50	5	2.68

Fisher, et al, Cancer 75:1310, 1995

SURGICAL MARGINS: DCIS in NSAPB B-17

Table 4. Adjusted Estimates of the Relative Risk of Second Ipsilateral Breast Tumors Related to Comedo Necrosis and Status of Lumpectomy Margins

Variable	Relative risk	95% confidence interval	P value
Comedo necrosis*	1.94	1.12-3.36	0.019
Margin status†	2.33	1.32-4.12	0.004

*Moderate/marked vs. absent/slight, adjusted for margin status and treatment.

† Free vs. uncertain/involved, adjusted for comedo necrosis and treatment.

Fisher, et al, Cancer 75:1310, 1995

SURGICAL MARGINS: DCIS in NSAPB B-17

Table 5. Average Annual Hazard Rate of Second Ipsilateral Breast Tumor Related to Margins of Resection and Comedo Necrosis

		L	umpectomy N	= 274	Lumpectomy + irradiation N = 299		
Specimen margins	Comedo necrosis	No. at risk	No. of events	Avg. annual rate/100	No. at risk	No. of events	Avg. Annual rate/100
Free	Absent/slight	125	9	1.97	144	6	1.18
Free	Moderate/marked	98	16	5.44	105	4	1.18
Uncertain/involved	Absent/slight	26	5	5.95	24	2	2.10
Uncertain/involved	Moderate/marked	25	8	10.46	26	3	3.28

"Most clinical investigators now agree that local recurrences after lumpectomy for DCIS most likely reflect residual disease and further that the acceptance of minimally clear margins is inadequate for local control." David Page and Michael Lagios

Fisher, et al, Cancer 75:1310, 1995

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PRIMARY TREATMENT



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MAY 13, 1999

NUMBER 19



THE INFLUENCE OF MARGIN WIDTH ON LOCAL CONTROL OF DUCTAL CARCINOMA IN SITU OF THE BREAST

MELVIN J. SILVERSTEIN, M.D., MICHAEL D. LAGIOS, M.D., SUSAN GROSHEN, PH.D., JAMES R. WAISMAN, M.D., BERNARD S. LEWINSKY, M.D., SILVANA MARTINO, D.O., PARVIS GAMAGAMI, M.D., AND WILLIAM J. COLBURN, M.D.

Silverstein, et al, NEJM 340:1455, 1999

VOLUME 340



Silverstein, et al, NEJM 340:1455, 1999



Silverstein, et al, NEJM 340:1455, 1999



Silverstein, et al, NEJM 340:1455, 1999

SURGICAL MARGINS: DCIS - Lumpectomy Alone

Univariate analysis of predictors of local recurrence of DCIS

	Total N/no. of events	Relative hazard ratio (95% confidence interval)	P value	Probability of remaining free of local recurrence at 5 years (±SE)	Probability of remaining free of local recurrence at 8 years (±SE)
Margin			<.001		
0 (transected)	32/15	1.00		48% ± 11%	$39\% \pm 12\%$
.19	53/18	.61 (.31-1.20)		$63\% \pm 8\%$	$58\% \pm 9\%$
1.0-1.9	20/7	.58 (.23-1.42)		73% ± 12%	49% ± 16%
2.0-2.9	82/20	.21 (.1042)		$81\% \pm 5\%$	$78\% \pm 5\%$
3.0-5.9	39/8	.35 (.1583)		64% ± 11%	$64\% \pm 11\%$
6.0-9.9	22/2	.20 (.0587)		$91\% \pm 9\%$	$61\% \pm 25\%$
≥10	197/9	.07 (.03–.15)		93% ± 3%	$91\%\pm 3\%$

"If wide margins are obtained, regardless of other factors, the probability of local recurrence remains small. With greater than 10-mm margins, the probability of remaining recurrence free at 8 years is greater than 90% without postoperative radiotherapy."

MacDonald, et al, Am J Surg 190:521, 2005

DUCTAL CARCINOMA IN SITU Lumpectomy without XRT

- Prosective, single arm trial:
 - DCIS of predominant grade 1 or 2
 - Mammographic extent of 2.5 cm
 - Final margins 1 cm or re-excision without residual DCIS
- Trial closed July 2002 at 158 patients:
 - Thirteen pts local recurrence at 7 to 63 months
 - Ipsilateral local recurrence 2.4% per patient-year
 - 5-year recurrence rate 12% (10/13 in same quadrant)

Wong (Joint Centers), et al., JCO 24:1031,2006

DUCTAL CARCINOMA IN SITU Multidisciplinary Selection

- 10 yr single institution experience
 - Group 1: ≥5-mm margin and received radiation
 - Group 2: \geq 10-mm margin and received no radiation
- 152 patients (153 cancers); median F/U 8.2 years
 - Overall, 6 recurrences (3.92%);
 - 1 of 71 recurred in group 1 (1.40%)
 - 5 of 82 recurred in group 2 (6.01%).
- CONCLUSION: A subgroup of DCIS patients can be identified in which radiation can be safely avoided.

West et al., Am J Surg 194:532,2007

CANCER PREVENTION METHODS

Prophylactic surgery Chemoprevention Behavior modification FUTURE: Gene therapy?



Invasive Breast Cancer



Noninvasive Breast Cancer



P-2 STAR Cumulative Incidence of Invasive Breast Cancer



P-2 STAR Cumulative Incidence of Invasive Breast Cancer



P-2 STAR Average Annual Rate and Number of Invasive Breast Cancers



P-2 STAR Average Annual Rate And Number Of Non-invasive (In Situ) Cancers





NCCN Guidelines Version 1.2012 **Breast Cancer**

DCIS POSTSURGICAL TREATMENT

SURVEILLANCE/FOLLOW-UP

Risk reduction therapy for ipsilateral breast following breast conserving surgery.

Consider tamoxifen for 5 years for: Patients treated with breastconserving therapy (lumpectomy) and radiation therapy (category 1), especially for those with ER-positive DCIS. The benefit of tamoxifen for ERnegative DCIS is uncertain Patients treated with excision alone

Risk reduction therapy for contralateral breast:

 Counseling regarding risk reduction See also NCCN Breast Cancer Risk **Reduction Guidelines**

- Interval history and physical exam every 6-12 mo for 5 y, then annually
- •Mammogram every 12 mo (and 6-12 mo postradiation therapy if breast conserved [category 2B])
- If treated with tamoxifen, monitor per **NCCN Breast Cancer Risk Reduction** Guidelines

DUCTAL CARCINOMA IN SITU Summary 1

- Minimally invasive perutaneous sampling should be used initially to make DCIS diagnosis.
- The extent of disease is the primary determinate of candidacy for breast conservation surgery.
- Standard imaging (mammo/US) should be used for EOD work-up; the role of MRI is controversial.
- SLN biopsy should be considered with mastectomy, in the event occult invasive cancer is found.
- The role of nipple-sparing mastectomy for DCIS is controversial, because patient selection is unclear.

DUCTAL CARCINOMA IN SITU Summary 2

- Surgical margins for DCIS are a concern because of known residual disease and local recurrence risk.
- Oncoplastic techniques can assist in the resection of segmentally distributed cancers.
- Radiation therapy helps compensate for narrow (but not positive) surgical margins.
- Patient selection for lumpectomy alone (no XRT) is challenging and significant disagreements abound.
- Endocrine therapy reduces risk recurrence of ER+ DCIS, and may help patients who forego XRT.







F.H.C.R.C.

BREAST CONSERVING RADIATION THERAPY



Skin bridge at seroma cavity is too narrow (2mm) for accelerated partial breast irradiation (APBI)



SLIDE CREDIT: Wendy Demartini **BASELINE MRI**



RIGHT 9 O'CLOCK KNOWN IDC

RIGHT LEVEL 1 AXILLA KNOWN METASTATIC LAN



SLIDE CREDIT: Wendy Demartini

LEFT 3 O'CLOCK NMLE 23 MM MRI BX = DCIS