

A randomized trial comparing axillary clearance versus no axillary clearance in older patients (≥ 60 years) with breast cancer:

First results of International Breast Cancer Study Group (IBCSG) Trial 10-93



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Aim and Background

- Axillary clearance is associated with undesirable side-effects
- We investigated if avoiding axillary surgery in older women with clinically N₀ disease would result in improved quality of life (QL) and similar disease-free survival (DFS) and overall survival (OS)



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Randomization

Breast Surgery with Axillary Clearance
(Ax) followed by Tam for 5 years

Versus

Breast Surgery followed by Tam for 5
years



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IBCSG Trial 10-93

Target accrual: 472

Actual accrual: 473

Years of accrual: 1993 - 2002

Median follow-up: 6 years



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Patient Characteristics

	Breast Surgery with Ax	Breast Surgery	Total
Total Cases	234	239	473
Median Age (years)	74 [60-91]	74 [60-91]	74 [60-91]
% ER-Positive	76%	84%	80%
% Node-Positive	27%	-	-
Median Number of Nodes Examined	13	-	-



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Patient Characteristics

	Breast Surgery with Ax	Breast Surgery	Total
%Received Hormonal Replacement Therapy	21%	22%	22%
% Mastectomy	45%	44%	45%
% Breast conserving surgery with Radiotherapy	33%	32%	33%
% Breast conserving surgery without Radiotherapy	22%	23%	23%



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Endpoints

- QL
 - Physician-reported
 - Patient self-assessment
- Axillary recurrence
- DFS/OS
- Sites of first event



Physician-Reported Side-Effects

Ipsilateral arm movement:

Restricted

Unrestricted

Arm pain:

Yes

No

Assessments

Baseline, post-operative and months 3, 6, 9, 12, 18, 24

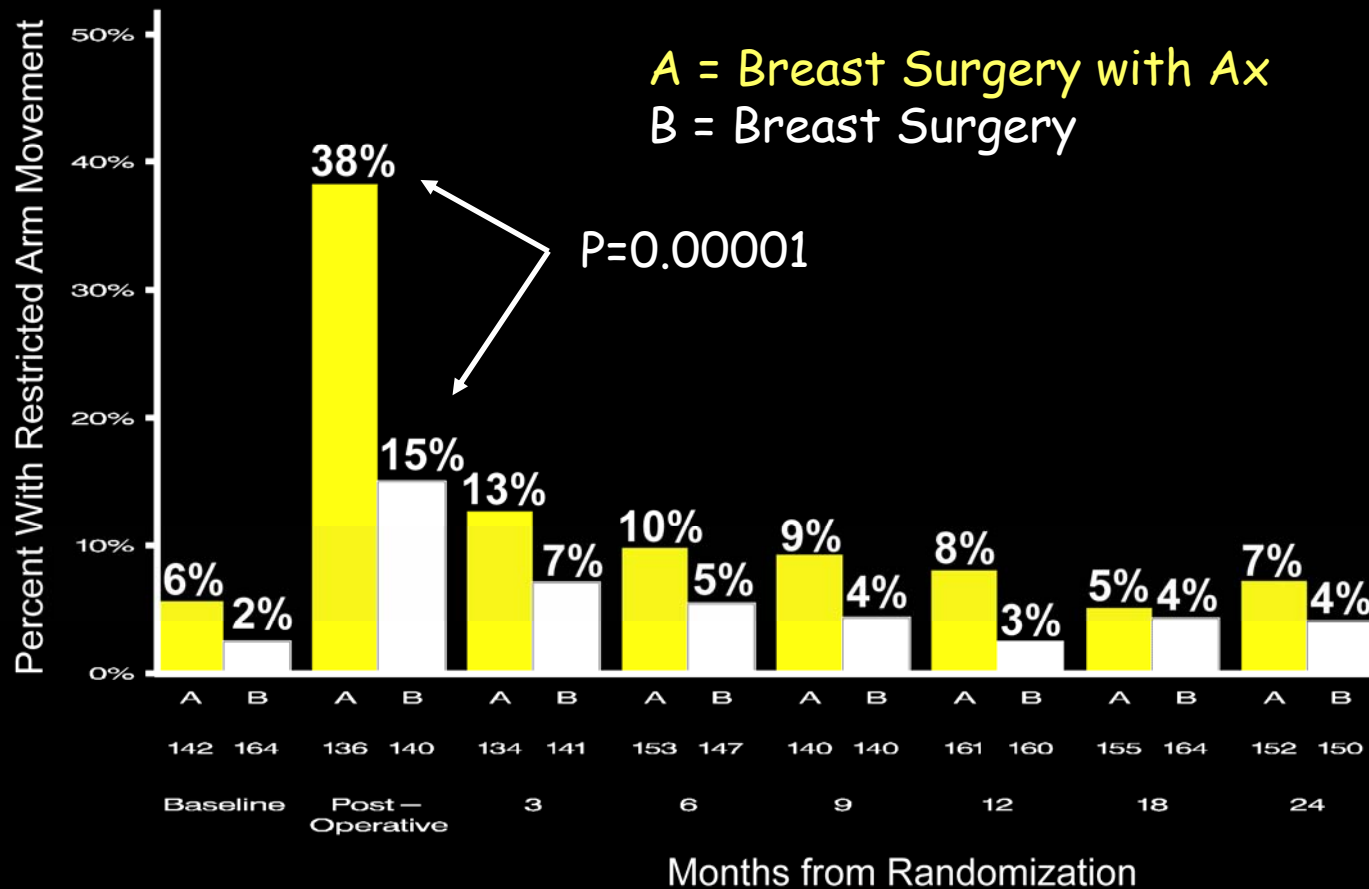


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Physician-Reported Restricted Arm Movement

(according to treatment and time from randomization)

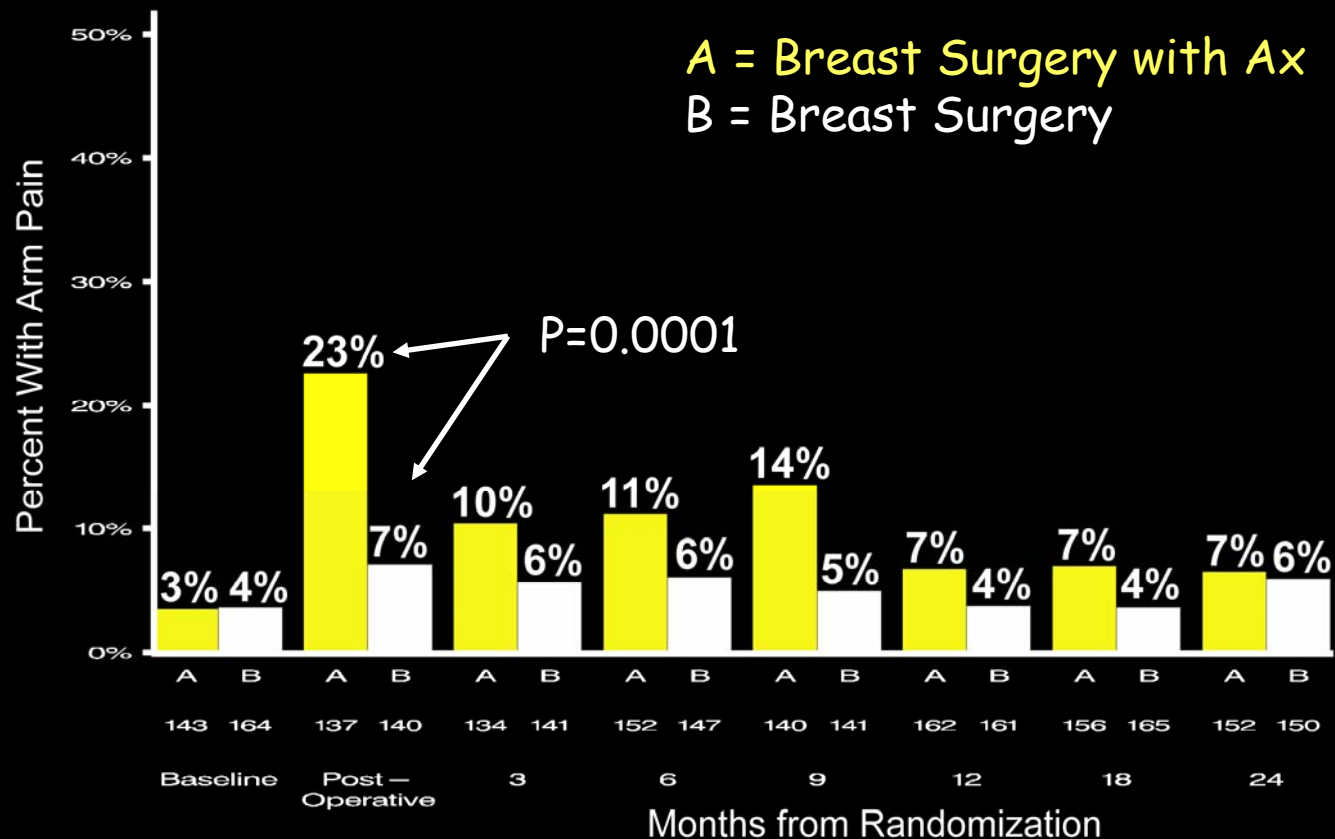


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Physician-Reported Arm Pain

(according to treatment and time from randomization)



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Patient Self-Assessment

"Overall, how much are you bothered by any problems with your hand, arm, shoulder or chest?"



"How much effort does it cost you to cope with your illness?"



Assessments

Baseline, post-operative and months 3, 6, 9, 12, 18, 24



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Patient Self-Assessment

Bothered: Hand, Arm, Shoulder or Chest

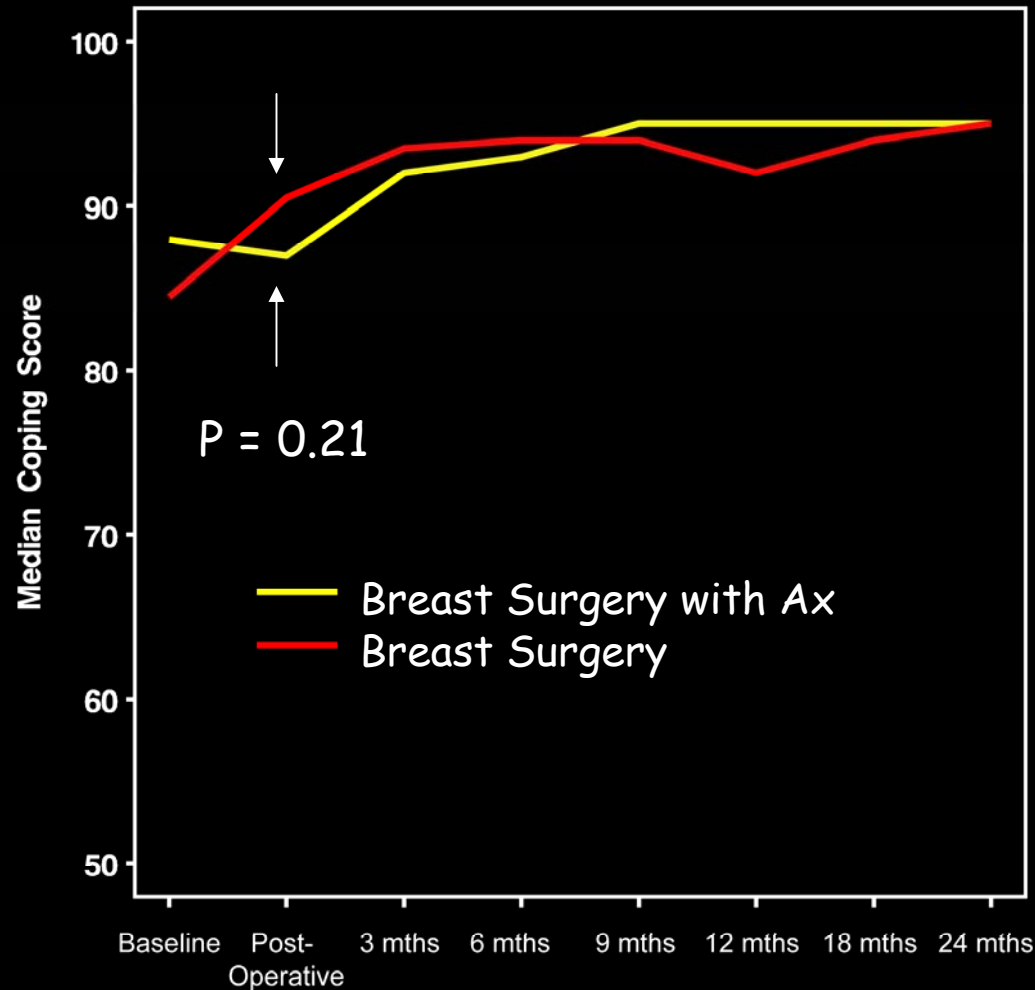


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Patient Self-Assessment

Coping



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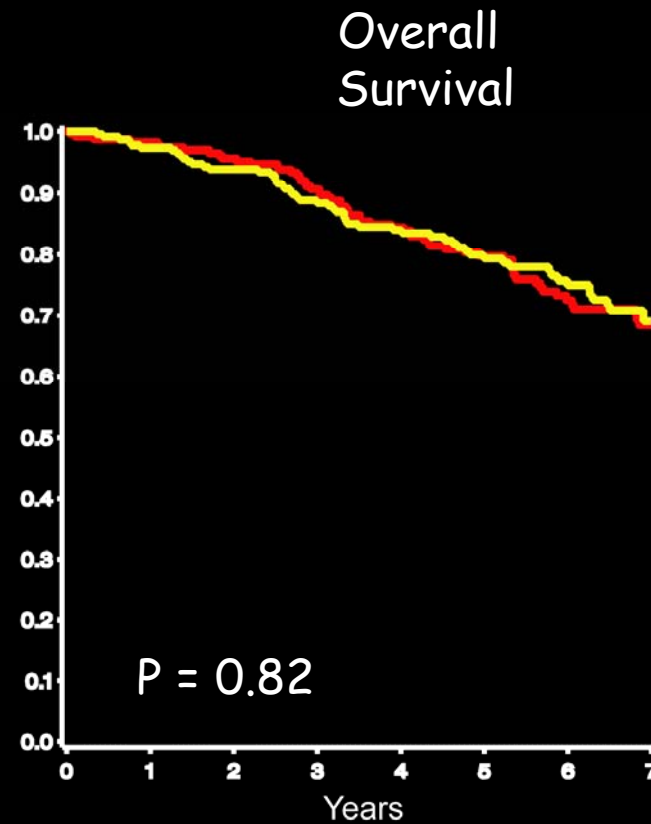
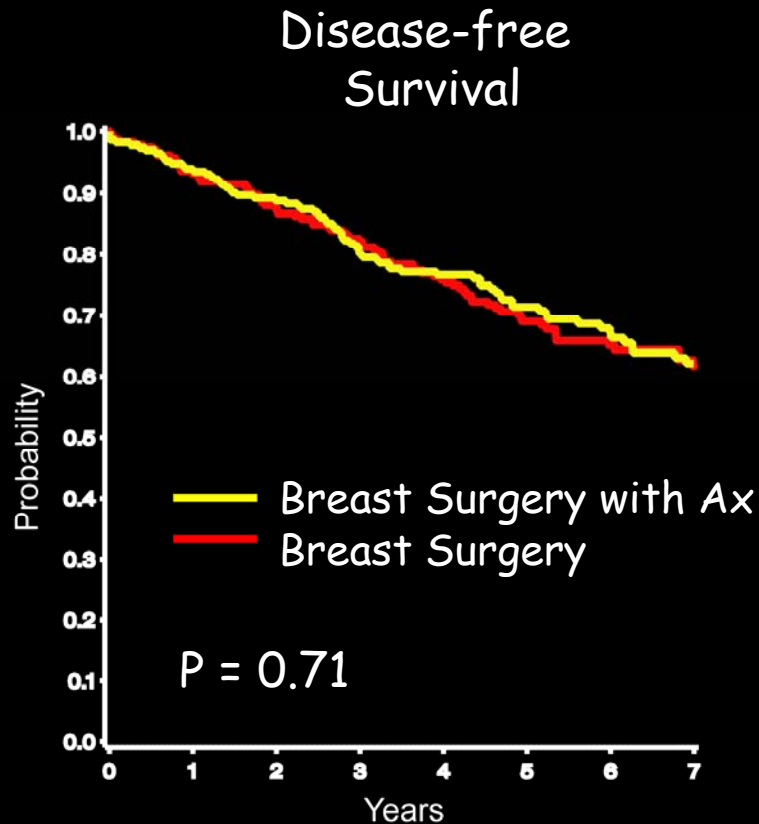
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Axillary Recurrences (6 Years Median Follow-up)

	Breast Surgery with Ax		Breast Surgery		Total	
Axillary Recurrences	2	(1%)	7	(3%)	9	(2%)



Disease-Free and Overall Survival



Treatment	Total Patients	Total Events	6-yr DFS% +/- SE	HR [Sx+Ax / Sx]	95% CI
Sx + Ax	234	90	67 +/- 3	1.06	0.79, 1.42
Sx	239	88	65 +/- 3		

Treatment	Total Patients	Total Events	6-yr OS% +/- SE	HR [Sx+Ax / Sx]	95% CI
Sx + Ax	234	71	75 +/- 3	1.04	0.75, 1.45
Sx	239	71	73 +/- 3		



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Sites of First Event

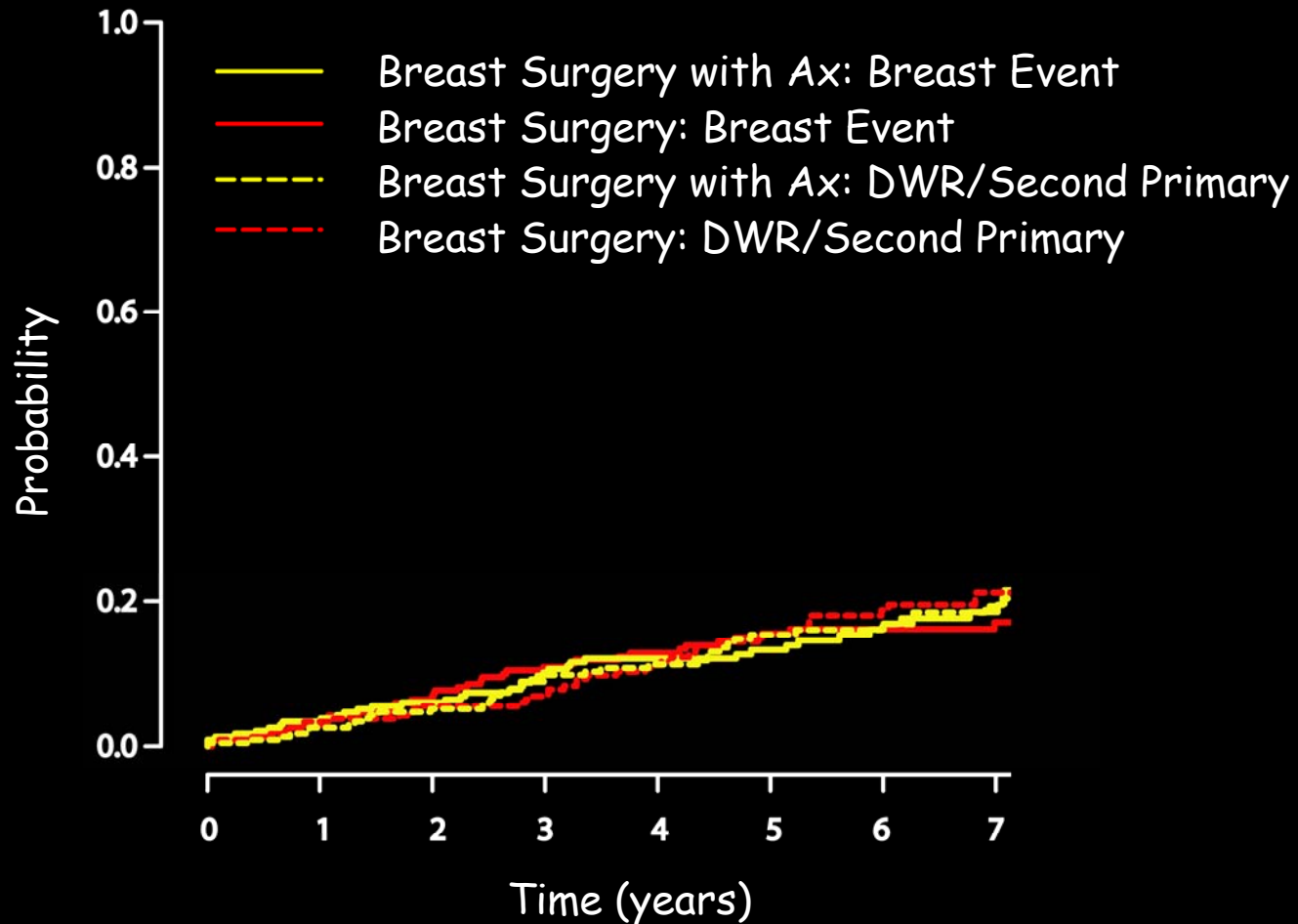
Sites	Breast Surgery with Ax		Breast Surgery		Total	
	N	(%)	N	(%)		
Local	9	(4)	4	(2)	13	(3)
Contralateral breast	2	(1)	4	(2)	6	(1)
Regional	2	(1)	6	(3)	8	(2)
Distant	29	(12)	23	(10)	52	(11)
Second primary	14	(6)	13	(5)	27	(6)
Death without recurrence	34	(15)	38	(16)	72	(15)

} 17% (Local, Contralateral breast, Regional, Distant)
} 21% (Second primary, Death without recurrence)



Cumulative Incidence of First Event According to Site

(6 Years Median Follow-up)



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Conclusions

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Avoiding axillary clearance for women ≥ 60 years old who have clinically N₀ disease and receive Tam results in improved QL with no apparent compromise in efficacy



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Thanks to patients,
investigators, nurses,
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allowing us to
understand and move
forward....