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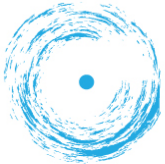


Eduardo Millen
Mastologista

www.eduardomilen.com.br
emillen@inca.gov.br

Sociedade Brasileira de Mastologia
Regional Rio de Janeiro

Axillary dissection vs. no axillary dissection in patients with cT1-T2 N0 breast cancer and micrometastases only in the sentinel node: ten-year results of the IBCSG 23-01 trial

Viviana Galimberti, MD
for the
International Breast Cancer Study Group

Background

- For patients with a metastatic sentinel node (SN), axillary dissection (AD) used to be the standard approach to the axilla
- Five-year results of 23-01 and 10-year results of Z0011 showed that, for patients with moderate axillary involvement, AD provided no advantage in terms of overall or disease-free survival, while axillary failure rates were low
- Updated follow-up of 23-01 was successful for 83% of patients who had not withdrawn

Study Design

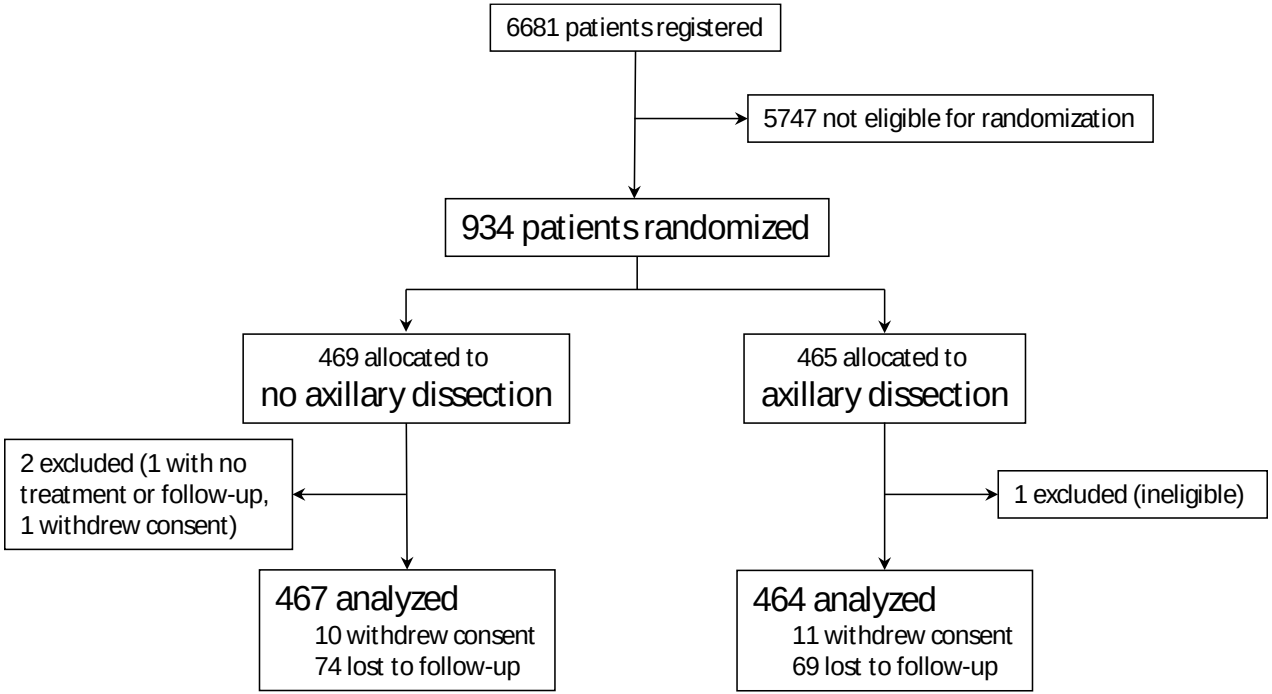
- Eligible consenting patients – who could be scheduled for mastectomy or conservative surgery – were registered before surgery
- If tumor/nodal eligibility criteria met, randomized:-
  - Prior to amendment (June 2006): Tumor size ≤ 3 cm; unicentric; one micrometastatic (≤2 mm) sentinel node; no extracapsular extension or macrometastatic involvement
  - After amendment: Tumor size ≤ 5 cm; uni or multicentric; one or more micrometastatic (≤2 mm) sentinel nodes

Statistical Considerations

- Primary endpoint: invasive disease-free survival (DFS)
- Secondary endpoint: overall survival, incidence of reappearance of tumor in un-dissected axilla
- The non-inferiority margin for no-AD vs. AD was defined as a DFS hazard ratio (HR, no-AD relative to AD) of <1.25, and was assessed using a z-test applied to the log HR.

CONSORT Diagram

(934 patients randomized from 2001 to 2010)



Patients lost or withdrawn were censored at last follow-up

Patient and Tumor Characteristics

Characteristic	AD (n=464)	No AD (n=467)	Total (n=931)
Age, years; median (range)	53 (28–81)	54 (26–81)	54 (26–81)
Menopausal status			
Pre	204 (44%)	207 (44%)	411 (44%)
Post	260 (56%)	260 (56%)	520 (56%)
Pre-op sentinel node biopsy			
No	287 (62%)	286 (61%)	573 (62%)
Yes	177 (38%)	181 (39%)	358 (38%)
Sentinel node disease			
≤ 1 mm	323 (70%)	320 (69%)	643 (69%)
1.1–2.0 mm	131 (28%)	135 (29%)	266 (29%)
>2 mm	10 (2%)	11 (2%)	21 (2%)
Unknown	0	1 (<1%)	1 (<1%)

Patient and Tumor Characteristics

Characteristic	AD (n=464)	No AD (n=467)	Total (n=931)
Tumor size			
<2 cm	316 (68%)	322 (69%)	638 (69%)
2 cm to 2.9 cm	106 (23%)	112 (24%)	218 (23%)
≥3 cm	35 (8%)	28 (6%)	63 (7%)
Unknown	7 (2%)	5 (1%)	12 (1%)
Tumor grade			
Grade 1	118 (25%)	90 (19%)	208 (22%)
Grade 2	214 (46%)	241 (52%)	455 (49%)
Grade 3	129 (28%)	135 (29%)	264 (28%)
Unknown	3 (<1%)	1 (<1%)	4 (<1%)

Patient and Tumor Characteristics

Characteristic	AD (n=464)	No AD (n=467)	Total (n=931)
ER status			
Negative	51 (11%)	40 (9%)	91 (10%)
Positive	**409 (88%)**	**425 (91%)**	**834 (90%)**
Unknown	4 (<1%)	2 (<1%)	6 (<1%)
PgR status			
Negative	108 (23%)	115 (25%)	223 (24%)
Positive	**352 (76%)**	**350 (75%)**	**702 (75%)**
Unknown	4 (<1%)	2 (<1%)	6 (<1%)

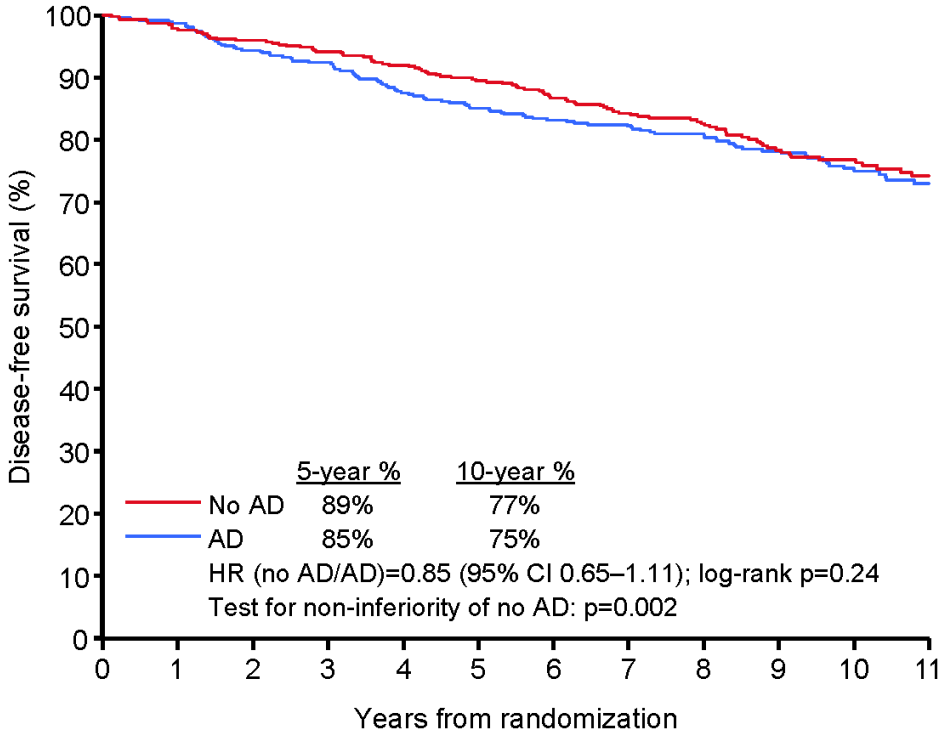
Local Treatment

Treatment	AD (n=464)	No AD (n=467)	Total (n=931)
Type of breast surgery			
Conservative	420 (91%)	425 (91%)	845 (91%)
Mastectomy	44 (9%)	42 (9%)	86 (9%)
Radiotherapy (BCS)			
No	10/420 (2%)	12/425 (3%)	22 (3%)
Yes	410/420 (98%)	413/425 (97%)	823 (97%)
Radiotherapy in mastectomy			
No	42/44 (95%)	39/42 (93%)	81 (94%)
Yes	2/44 (5%)	3/42 (7%)	5 (6%)

Systemic Treatment

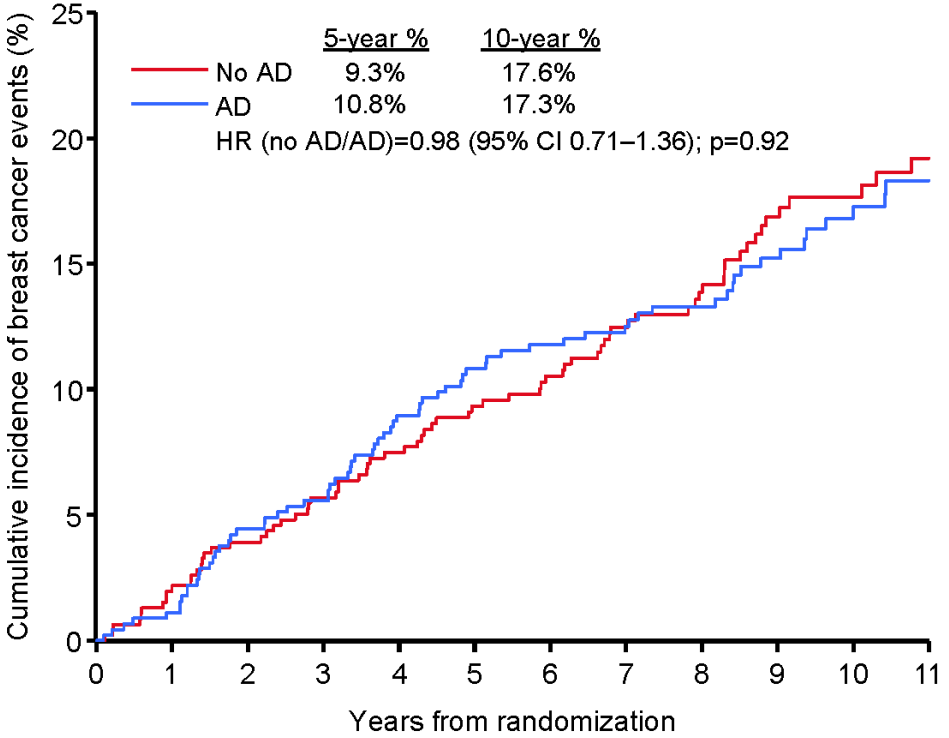
Treatment	AD (n=464)	No AD (n=467)
Any systemic therapy	441 (95%)	451 (97%)
Hormonal therapy only	292 (63%)	315 (67%)
Chemotherapy only	42 (9%)	33 (7%)
Combination therapy	107 (23%)	103 (22%)

Disease-Free Survival



Number at risk												
No AD	467	455	443	428	412	389	367	336	278	215	168	131
AD	464	456	433	419	392	371	353	335	282	231	169	130

Cumulative Incidence of Breast Cancer Events



Disease-Free Survival Events and Deaths

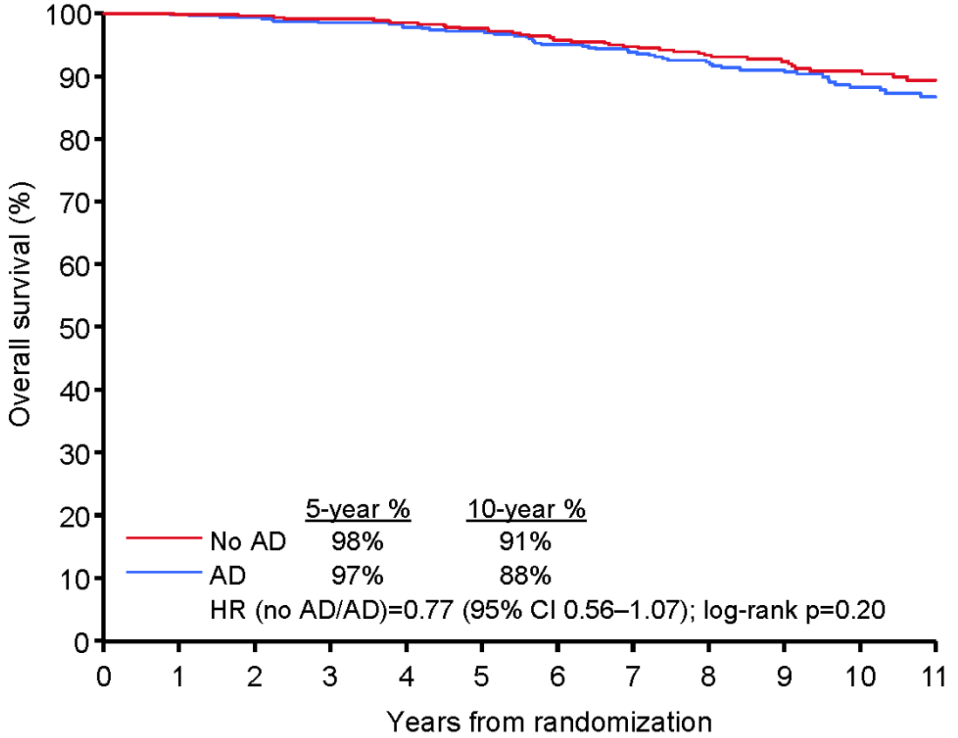
	AD (n=464)		No AD (n=467)	
Total DFS events	117	25.2%	101	21.6%
Breast cancer events	**75**	**16.2%**	**74**	**15.8%**
Local	13	2.8%	14	3.0%
Regional	3	0.6%	9	1.9%
Ipsilateral axillary events	2	0.4%	8	1.7%
Distant	47	10.1%	41	8.8%
Contralateral breast	12	2.6%	10	2.1%
Non-breast cancer events	**42**	**9.1%**	**27**	**5.8%**
Second (non-breast) primary	23	5.0%	17	3.6%
Death without prior cancer event	2	0.4%	6	1.3%
Death with unknown cancer status	17	3.7%	4	0.9%
Deaths	**58**	**12.5%**	**45**	**9.6%**

Disease-Free Survival Events According to Type of Surgery

	Mastectomy (n=86)		Breast conservation (n=845)	
Total DFS events	23 (26.7%)		195 (23.1%)	
Breast cancer events	17 (19.8%)		132 (15.6%)	
Ipsilateral axillary events	2		8	
	AD 1 (1.2%)	No AD 1 (1.2%)	AD 1 (0.1%)	No AD 7* (0.8%)
Non-breast cancer events	6 (7.0%)		63 (7.5%)	
Deaths	14 (16.3%)		89 (10.5%)	

*Five received intraoperative radiotherapy

Overall Survival



Number at risk												
No AD	467	464	460	451	441	424	405	375	314	257	197	158
AD	464	461	456	446	438	422	401	379	319	264	199	156

Summary

After a median follow-up of 9.8 years:

- ✓ No difference between the groups for main endpoint (DFS) or secondary endpoint OS
- ✓ Rate of axillary failure in no AD arm was low at 1.7% (0.8% in BCS)

Conclusions

- Our findings are fully consistent with those of the Z0011 trial, which after 10 years found no differences between the AD and no AD groups for any endpoint in patients with moderate disease burden in the axilla, undergoing conservative breast surgery
- We also suggest that non AD is acceptable treatment in patients scheduled for mastectomy
- Our data fully support the change in clinical practice that started after the early published results
- No AD is now standard treatment in early breast cancer when the SN is only minimally involved

OBRIGADO

Eduardo Millen
Mastologista

emillen@inca.gov.br
eduardomillen@gmail.com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