

Table S1 Axillary nodal burden and axillary recurrence rates in the trials of more vs. less (or no) axillary surgery

Trial	Setting	Control arm [n]	Intervention arm [n]	Control arm axillary metastasis*, n/N (%) ^ε	Axillary RT ^a	Regional recurrence [§]		Distant recurrence	
						Control arm	Intervention arm	Control arm	Intervention arm
NSABP-B04 (14,15)	Operable breast cancer	Radical mastectomy [362]	Total mastectomy [365]	~40%	A third arm, not compared here	15 (4.1%)	26 (6.3%) ^β	101 (28%)	107 (29%)
IBCSG-10-93 (16)	>60 years, T1–2 node negative	ALND [234]	No ALND [239]	64/230 (28%)	Unclear	2 (0.9%)	2 (0.9%)	29 (12%)	24 (10%)
IBCSG-023-01 (17)	Operable breast cancer, cN0 and pNmi (Sn) ≥1	ALND [464]	No ALND [467]	59/447 (13%)	Not allowed; but 5% in intervention arm and 4% in ALND arm received	1 (0.2%)	1 (0.2%)	41 (9%)	47 (10%)
ACOSOG-Z0011 (4,18)	Operable breast cancer, cN0 and pN+ (Sn) 1–2	ALND [420]	No ALND [436]	27.3%	Possibility of field adjustment	0	0	21.8% [‡]	19.8% [‡]
AMAROS (2)	Operable breast cancer, cN0 and pN+ (Sn) 1–2	ALND [744]	Axillary RT [681]	220/672 (33%)	Intervention arm	4 (0.5%)	4 (0.5%)	25% [‡]	29.9% [‡]
SINODAR-ONE (19)	Operable breast cancer, cN0 and pN+ (Sn) 1–2	ALND [403 ^ε]	No ALND [419 ^ε]	193/439 (44%)	None	1 (0.2%)	1 (0.2%)	7 (1.6%)	8 (1.8%)
SOUND (5)	≤2 cm (up to T1) primary with cN0	SLNB [708]	No axillary surgery [697]	97/708 (13.7%)	Details unavailable	12 (1.7%)	12 (1.7%)	13 (1.8)	14 (2.0)
SENOMAC (20)	cT1–3N0 and pN+ (Sn) 1–2	ALND [1,205]	SLNB [1,335]	403/1,167 (34.5%)	~80% of intervention arm	6 (0.5%)	6 (0.5%)	53 (4.4)	44 (3.3)
OTOASAR (88)	T 3 cm, cN0 and pN+ (Sn)	ALND [1,054]	SLNB f/b axillary RT [1,052]	94/244 (38.5%)	All in interventional arm and 57 (23.3%) patients of control arm	5 (2%)	5 (2%)	27.9% [®]	22.6% [®]
INSEMA (21)	cT1–2, cN0, undergoing breast conservation. pN1 in SLNB group were further randomized to ALND vs. no ALND	SLNB [3,896]	No axillary surgery [962]	446/3,275 ^ε (13.6%)	Incidental axillary radiotherapy to level I & II while irradiating breast	12 (0.3%)	12 (0.3%)	104 (2.7)	26 (2.7)

*, cumulative nodal burden including additional nodal burden on ALND if it was after SLNB (where reported). ^ε, per-protocol. [§], intention-to-treat. ^a, in the arm with no ALND. ^β, 68/365 (18.6%) underwent delayed ALND for subsequent development of positive node (median time 14.8 months). ^ε, after exclusion of ineligible patients. [‡], breast cancer events at 10 years (distant recurrences not reported separately). [®], breast cancer events at 8 years (distant recurrences not reported separately).

References

88. Sávolt Á, Péley G, Polgár C, et al. Eight-year follow up result of the OTOASOR trial: The Optimal Treatment Of the Axilla - Surgery Or Radiotherapy after positive sentinel lymph node biopsy in early-stage breast cancer: A randomized, single centre, phase III, non-inferiority trial. Eur J Surg Oncol 2017;43:672-9.