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Recurrence-free survival following sentinel node-positive breast cancer without completion axillary lymph node dissection – first results from the international randomized SENOMAC trial

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Disclosure Information

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Jana de Boniface

I have no financial relationships to disclose.

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- ACOSOG Z0011 results first published in 2010 & 2011
- EORTC 10981-22023 AMAROS in 2014
- Uncertainties regarding
 - Statistical power
 - Patient selection
 - Radiotherapy fields
 - Relevant subgroups: older patients, patients receiving mastectomy, larger tumors, macro- versus micrometastases

- Prospective 1:1 randomized clinical non-inferiority trial
 - **Standard of Care:** Completion axillary dissection
 - **Intervention:** No completion axillary dissection
- Primary endpoint: Overall Survival
- Non-inferiority margin 2.5% (hazard ratio 90% CI below 1.44)
- Target accrual 3000 patients
 - 190 events required for statistical power
- **Secondary endpoint: Recurrence-Free Survival**

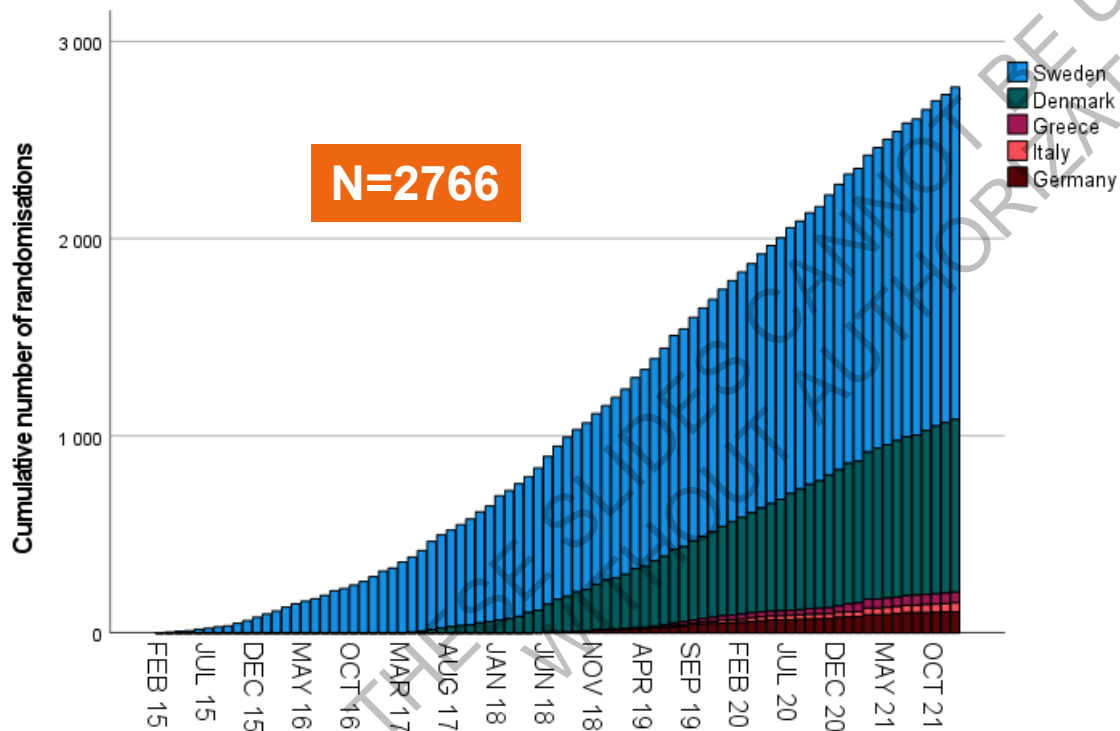
Patient Selection

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- T1-T3 primary invasive breast cancer
- Clinical node negativity (palpation)
 - Mandatory preoperative axillary ultrasound
- Male & female patients
- Breast-conserving surgery and mastectomy
- Up to 2 sentinel lymph node macrometastases
- No medical contraindications to adjuvant radiotherapy or relevant systemic treatment

Enrolment

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Results: Population

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- Per-protocol population N=2540
 - **Standard of Care** N=1205
 - **Intervention** N=1335
- Median follow-up 47 months (2-95)
- Median age 61 years (20-94)
 - Age 65 years or above in 1025 patients (40%)
- Ten male patients (0.4%)

Results: Tumor

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- Median tumor size 20 mm (0.2-155 mm)
 - T3 in 147 patients (5.8%)
- Lobular carcinoma in 504 patients (19.8%)
- Estrogen receptor positive & HER2 negative in 2200 patients (86.6%)

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Results: Axilla

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- 1 sentinel lymph node macrometastasis in 2151 patients (84.7%)
- Extranodal extension in 870 patients (34.3%)
- Removed lymph nodes median 15 (1-51) *versus* 2 (1-15)
- Additional sentinel lymph node micrometastases in 261 patients (10.2%)

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Results: Axilla

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Patient-reported outcomes one year after positive sentinel lymph node biopsy with or without axillary lymph node dissection in the randomized SENOMAC trial

Matilda Appelgren^{a,*}, Helena Sackey^{a,b}, Yvonne Wengström^{c,d}, Karin Johansson^e, Johan Ahlgren^{f,g}, Yvette Andersson^{h,i}, Leif Bergkvistⁱ, Jan Frisell^b, Dan Lundstedt^j, Lisa Rydén^{k,l}, Malin Sund^{m,n}, Sara Alkner^o, Birgitte Vrou Offersen^{p,q,r}, Tove Filtenborg Tvedskov^s, Peer Christiansen^{r,t}, Jana de Boniface^{a,u}, on behalf of the SENOMAC Trialists' Group

Results: Axilla

- Non-sentinel lymph node (SLN) metastases on axillary dissection in 403 patients (34.5%)
 - If 1 SLN met: 31.3%
 - If 2 SLN met: 51.3%
- Pathological nodal stage (primary surgery)

	Standard of Care	Intervention
pN1	1016 (84.3%)	1311 (98.2%)
pN2	116 (9.6%)	7 (0.5%)
pN3	35 (2.9%)	0 (0%)

Results: Treatment

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- Mastectomy in 920 patients (36.2%)
- Adjuvant radiotherapy including nodal target volumes in
 - **Standard of Care** N=1060 (88.0%)
 - **Intervention** N=1193 (89.4%)
- Systemic treatment in all but 27 patients
 - Chemotherapy N=1649 (64.9%)
 - Endocrine treatment N=2335 (91.9%)
 - HER2-targeted therapy N=224 (8.8%)

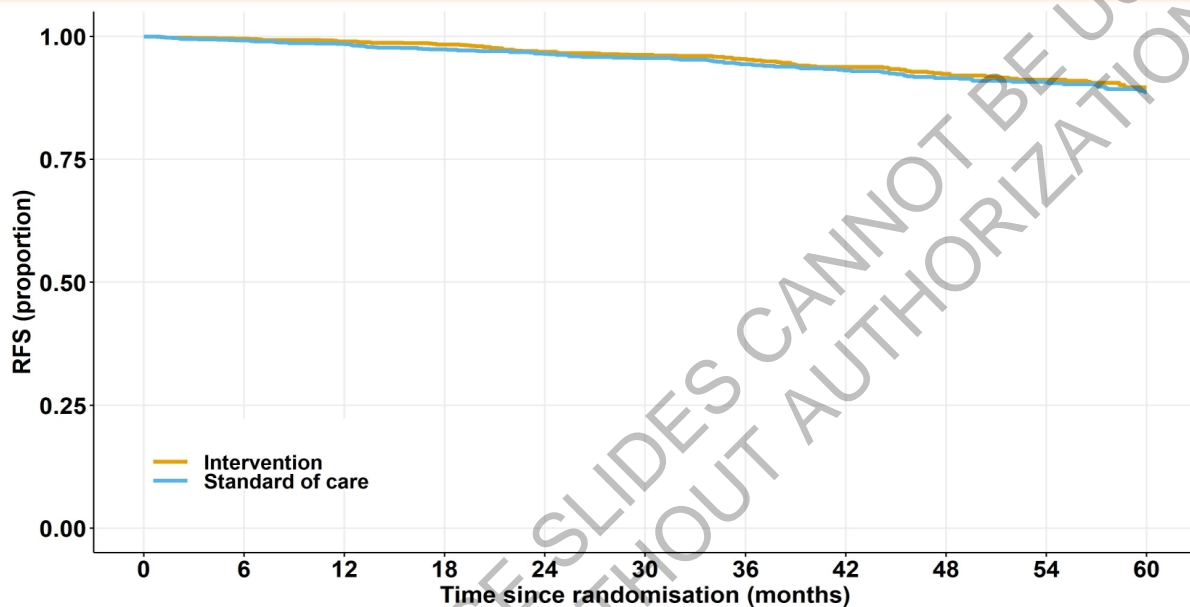
Recurrence-Free Survival

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- 191 Recurrence-Free Survival (RFS) events
 - **Standard of Care** N=96 (8.0%)
 - **Intervention** N=95 (7.1%)
- Estimated 5-year RFS
 - **Standard of Care** 88.7% (86.3-91.1)
 - **Intervention** 89.7% (87.5-91.9)

Recurrence-Free Survival

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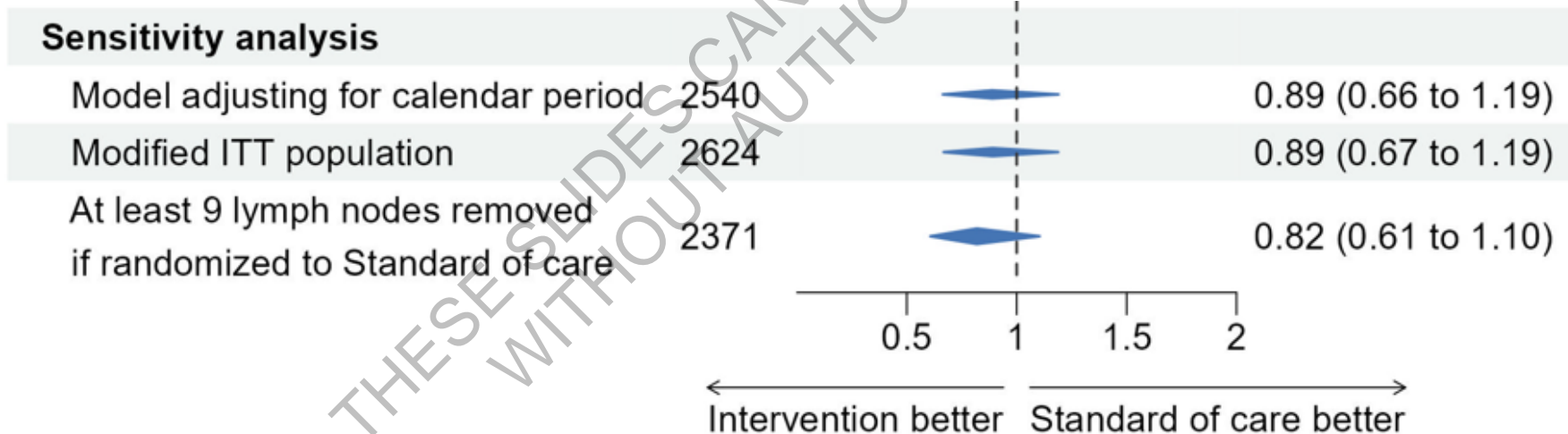
Number at risk

—	1335	1276	1069	832	577	307
—	1205	1159	1009	772	544	274

Results: Non-inferiority

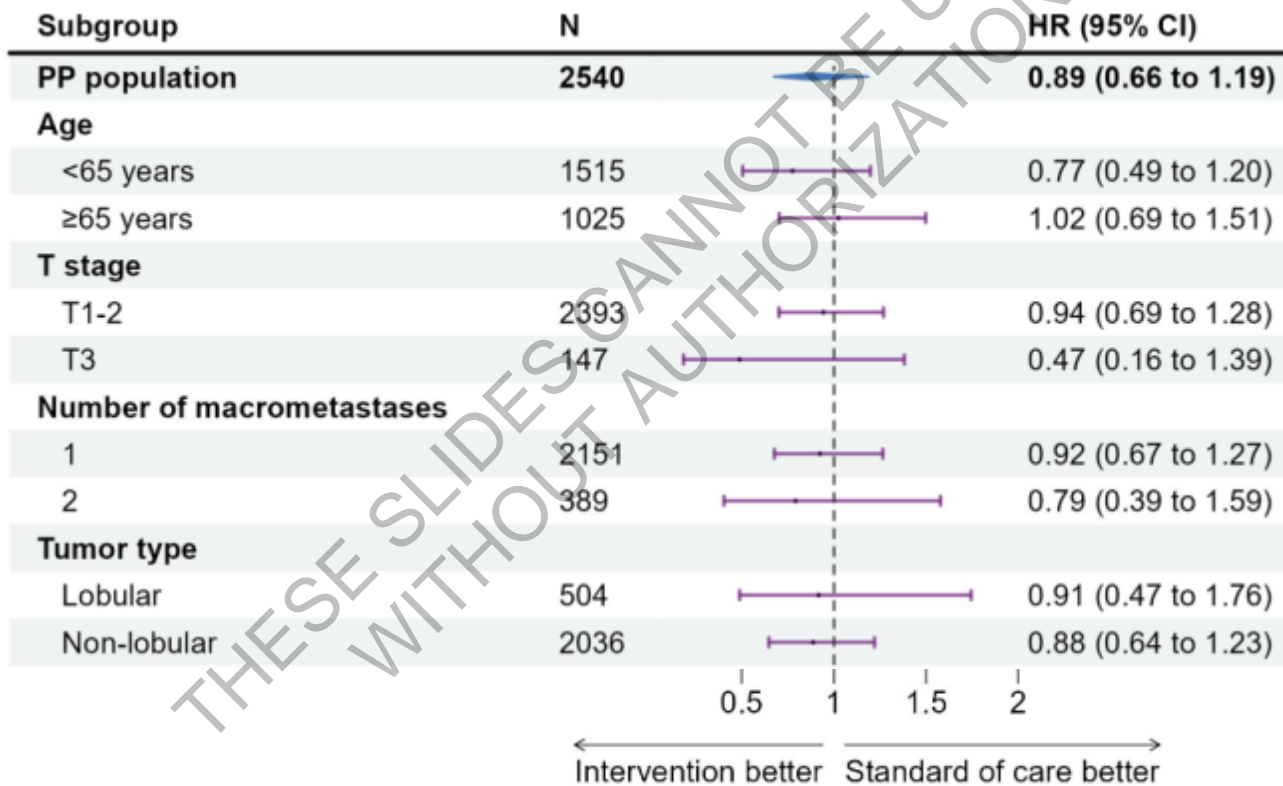
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- Hazard ratio 0.89 (0.66-1.19)
- Test of non-inferiority $p < 0.001$



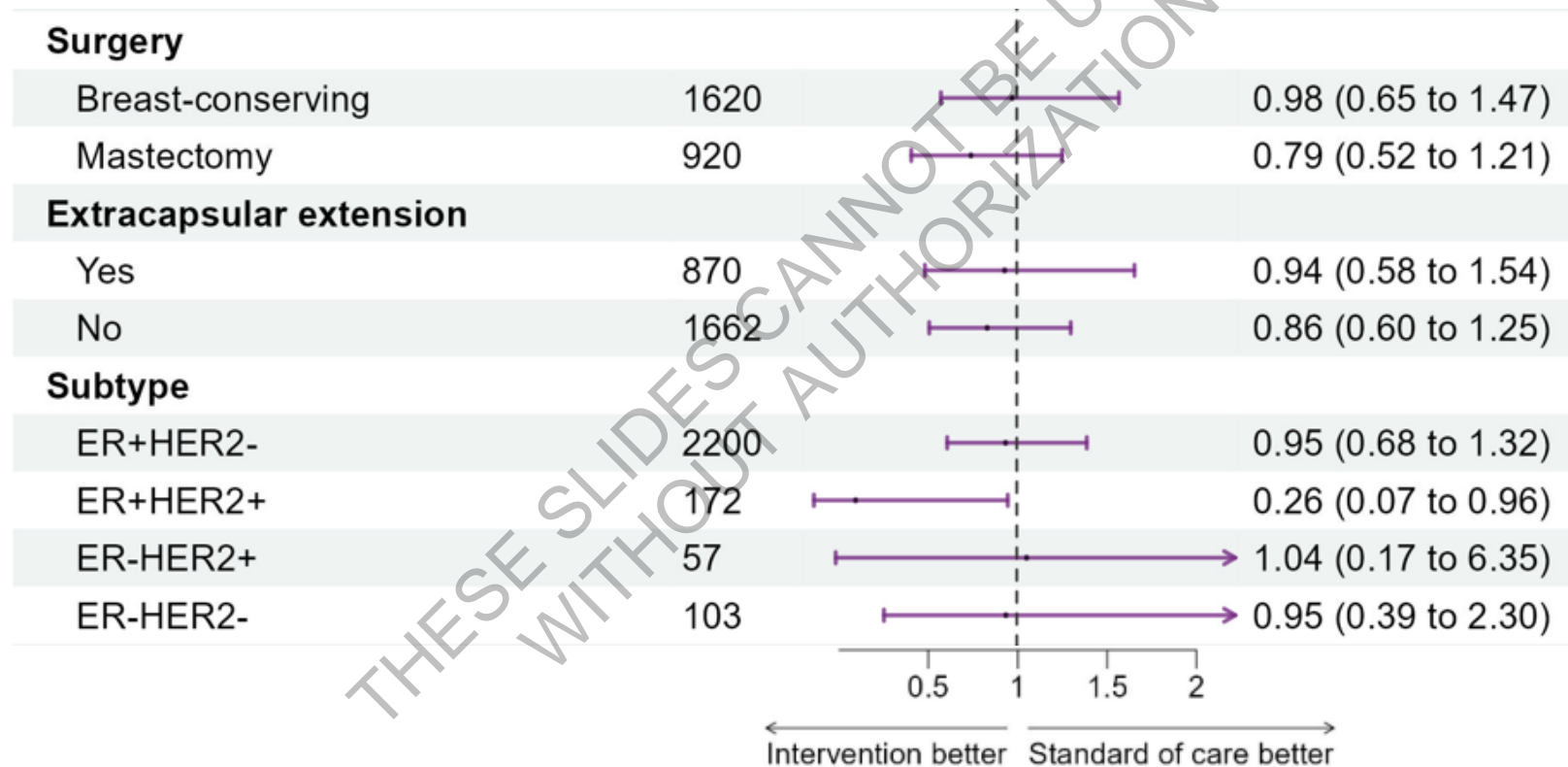
Subgroup analyses

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Subgroup analyses

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Conclusion

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- Non-inferiority of the omission of axillary dissection confirmed
 - High proportion of nodal irradiation
 - Systemic treatment as indicated by guidelines
 - Clinically relevant subgroups
- Narrow confidence interval significantly below non-inferiority margin suggests robust data

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Thank you

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Patients, staff, and research teams at 67 hospitals in 5 countries

SENOMAC Trialists: Jana de Boniface, Jan Frisell, Leif Bergkvist, Yvette Andersson, Sara Alkner, Dan Lundstedt, Roger Olofsson Bagge, Lisa Rydén, Malin Sund, Peer Christiansen, Tove Filtenborg Tvedskov, Birgitte Vrou Offeren, Thorsten Kühn, Toralf Reimer, Oreste Davide Gentilini, Michalis Kontos

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