

The SENOMAC trial - arm morbidity and HRQoL

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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

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Health Related Quality of Life (HRQoL) – what do we mean?

HRQoL

- An individual's perception of their life situation in relation to goals and expectations, but also in relation to positive and negative aspects of physical and mental health¹.

1. www.WHO.int; www.EORTC.org

How to measure HRQoL and arm morbidity?

Subjective measures

- Questionnaires
(HRQoL, arm morbidity)

Objective measures

- Arm volume
- Arm mobility

Patient reported outcomes (PROMs) or objectively measured outcomes -or both?

- Patient reported arm symptoms does not necessarily align with objectively measured symptoms¹.
- Decreased HRQoL correlated to patient reported arm swelling but not to objectively measured arm swelling².

1. Lucci et al., 2007, McLaughlin et al., 2008; Sackey et al., 2015; Wetzig et al., 2017, 2. Sackey et al., 2015

Why are patient-reported outcomes important?

Axillary Lymph Node Dissection (ALND) results in symptoms among 15-50% patients¹

- arm swelling / lymphoedema
- numbness
- pain
- restricted mobility

→ Impact on daily life, delayed return to work, decreased physical activity²

1. Ashiga et al., 2010; del Bianco et al., 2008; Donker et al., 2014; Sackey et al., 2014; Savolt et al., 2017; Wetzig et al., 2017
2. McLaughlin et al., 2008; Nesvold et al., 2010; Smidt et al., 2019; Zomkowski et al., 2018

PROMs in the SENOMAC trial

EORTC QLQ-C30	EORTC-BR 23	Lymph-ICF
Quality of life among cancer patients (all cancer types)	Function and symptoms after breast cancer treatment	Arm morbidity specific questionnaire after breast cancer treatment

- Early postoperative measurement
- 1 year
- 3 years
- 5 years
- 10 years



All patients from Denmark and Sweden who reached **1-year follow-up** June 2020 (N= 1181)

Response rate of 82.6 %
=> 976 questionnaires

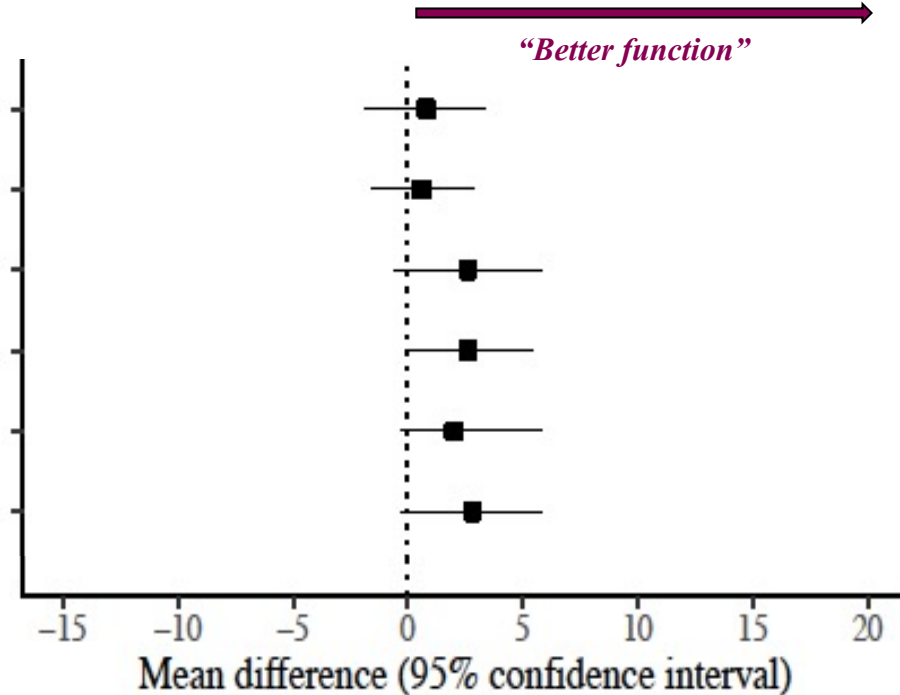
SLNB + ALND (standard)
(N=475)

SLNB only (intervention)
(N=501)

EORTC QLQ-C30: function

Function scales:

Global health / QoL	0.8	(-1.9,3.4)
Physical function	0.6	(-1.6,2.9)
Role function	2.6	(-0.6,5.8)
Emotional function	2.6	(-0.1,5.4)
Cognitive function	2	(-0.3,5.8)
Social function	2.8	(-0.3,5.8)



Global health / QoL:

“How would you rate your overall health during the past week?”

“How would you rate your overall quality of life during the past week?”

Very poor (0) ↔ Excellent (100)

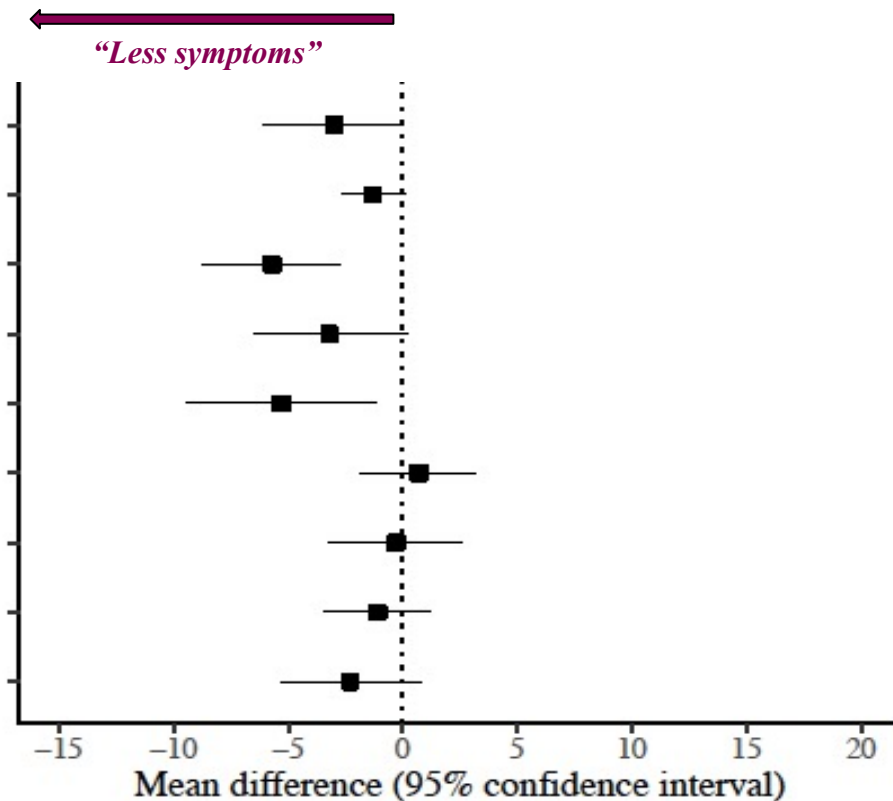
SLNB only: 74.4 vs ALND: 73.8, $P = .307$

EORTC QLQ-C30: symptoms

Symptom scales:

Fatigue	-3	(-6.1,0)
Nausea/vomiting	-1.3	(-2.6,0.1)
Pain *	-5.7	(-8.7,-2.7)
Dyspnea	-3.2	(-6.5,0.2)
Insomnia	-5.3	(-9.4,-1.2)
Appetite loss	0.7	(-1.9,3.2)
Constipation	-0.3	(-3.2,2.6)
Diarrhea	-1.1	(-3.4,1.2)
Financial difficulties	-2.3	(-5.3,0.8)

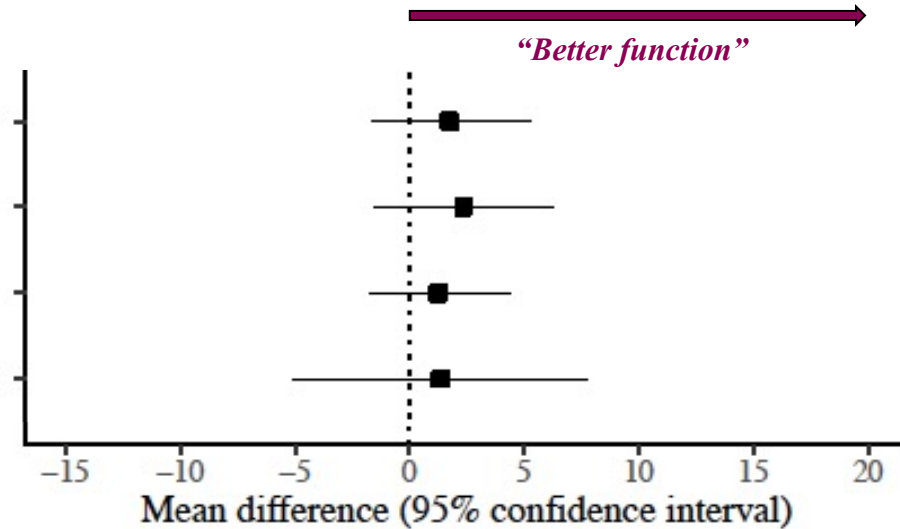
* $P < 0.001$



EORTC QLQ-BR23: function

Function scales:

Body image	1.7	(-1.7,5.2)
Future perspective	2.3	(-1.6,6.2)
Sexual function	1.2	(-1.8,4.3)
Sexual enjoyment	1.3	(-5.1,7.7)



EORTC QLQ-BR23: symptoms

Symptom scales:

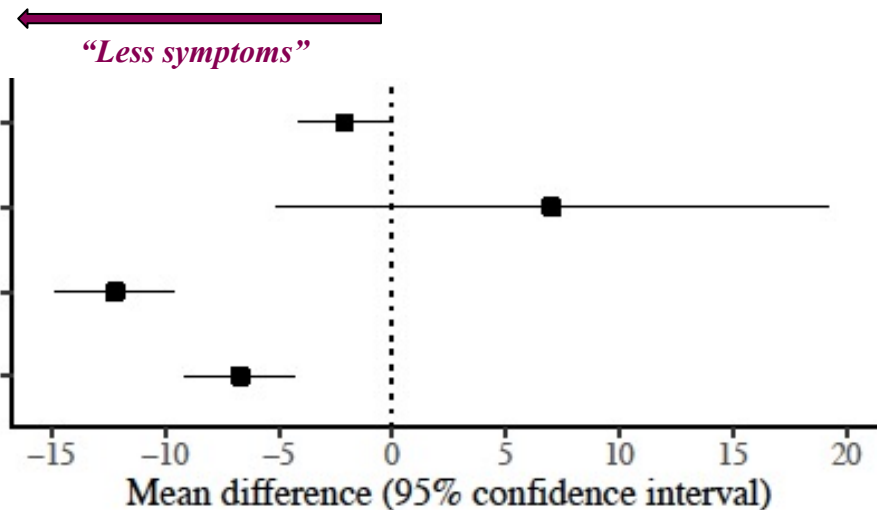
Systemic therapy side effects -2.1 (-4.1,0)

Upset by hair loss 7 (-5.1,19.2)

Arm symptoms * -12.2 (-14.8,-9.6)

Breast symptoms * -6.7 (-9.1,-4.3)

* $P < 0.001$



Lymph-ICF

Lymph-ICF total score * -6.8 (-8.8,-4.7)

Physical function * -11.2 (-13.7,-8.8)

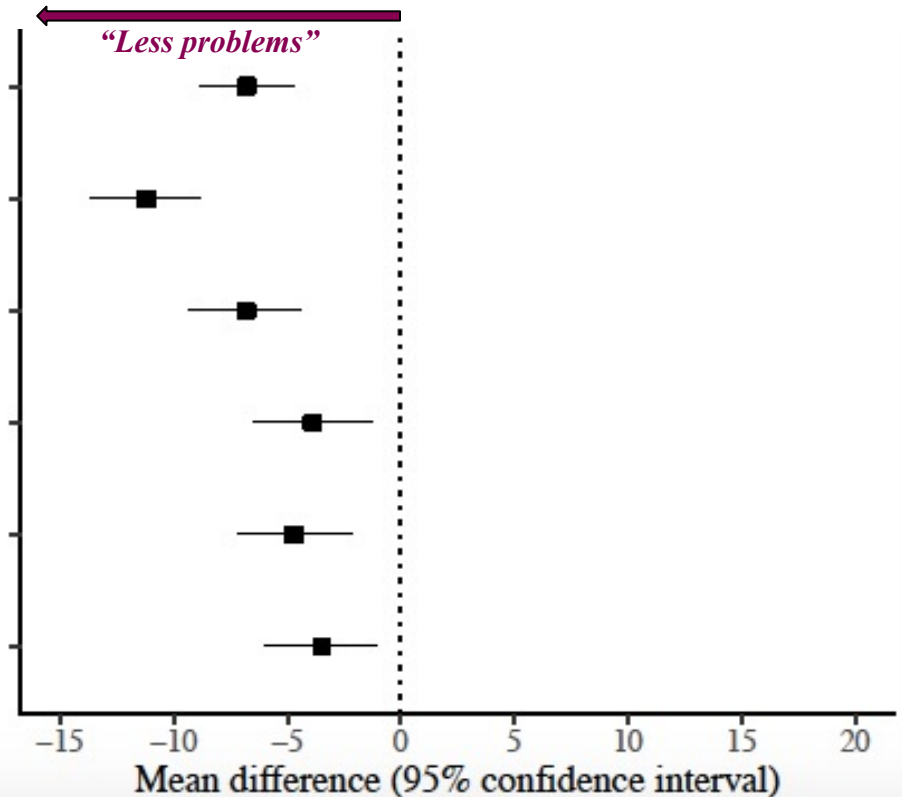
Mental function * -6.8 (-9.3,-4.4)

Household activities * -3.9 (-6.5,-1.3)

Mobility activities * -4.7 (-7.2,-2.2)

Life and social activities * -3.5 (-6,-1.1)

* $P \leq 0.001$



Physical function

Does your arm:

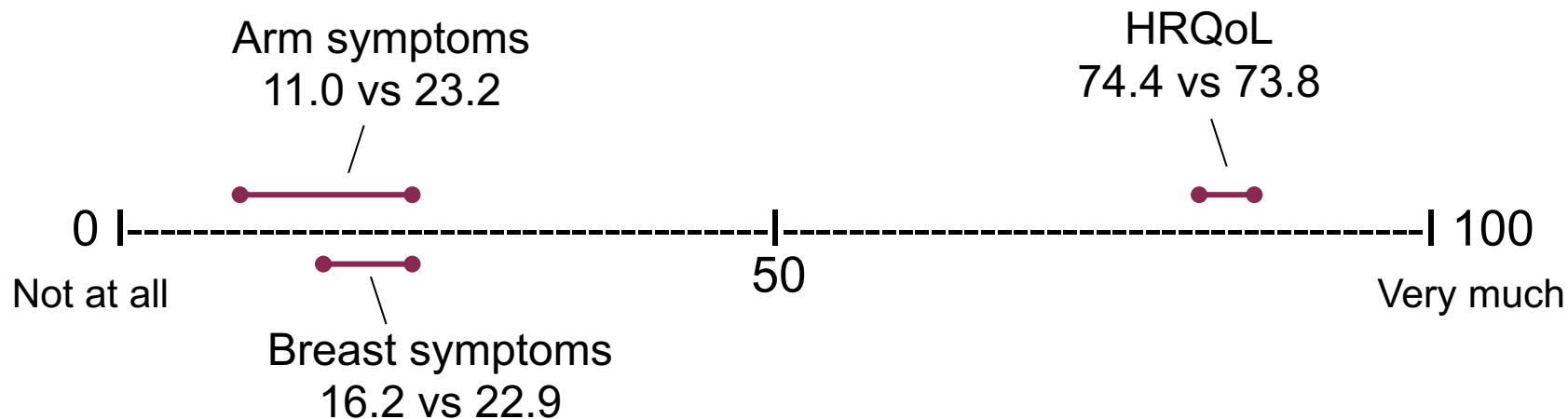
*“Feel heavy?”, “Feel stiff?”, “Feel” swollen?, “Feel like it has lost strength?”,
“Tingle?”, “Hurt?”, “Have a tensed skin?”*

Not at All (0) ←→ Very Much (100)

SLNB only: 9.1 vs ALND: 20.4, $P < .001$

But how severe are these problems?

Adjusted mean scores SLNB only vs ALND



Lymph-ICF: categories

PHYSICAL FUNCTION



SLNB only
(n=501)

SLNB+ALND
(n=475)

87.7%

“No or small problem”

66.8%

12.3 %

8.6%

3.7%

“A moderate problem”

20.2%

“A severe or a very severe problem”

13.0%

33.2 %

To conclude...

- Significantly less arm morbidity after SLNB alone
- No HRQoL difference
- Focus group interviews, SENOMAC participants (Sweden)
- Arm volume and arm mobility, a limited SENOMAC population (Stockholm)

Take home message

Patient-reported outcomes are highly relevant in de-escalation of axillary surgery

- Identify axillary staging method with least impact on patient's daily life
- 3- and 5-year follow-up for long-term impact on arm morbidity and HRQoL
- Develop and improve the patient-centered support and information

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