SWEDEPAD

SWedish Drug-Elution trial in Peripheral Arterial Disease

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

What is a proper outcome measure for PAD treatment

Late lumen loss?

Primary patency?

Target lesion revascularisation?

Binary restenosis?

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SURROGATES!

Intermittent claudication

Improved quality of life

Critical limb ischemia

Avoid amputation

Registries

Randomized Studies (RCT)

RRCT!

Register

RCT

A **new** clinical trial design;
The ***Register*** based randomized trial (*R*RCT)

Combining an established registry with
an online randomization function

Allows large clinical trials

The **Swedvasc** registry
records 3000 infrainguinal
endovascular procedures/year

SWEDEPAD

Inclusion criteria

Symptomatic PAD caused by >50% stenosis or occlusion of infrainguinal arteries and eligible for endovascular treatment

Exclusion criteria

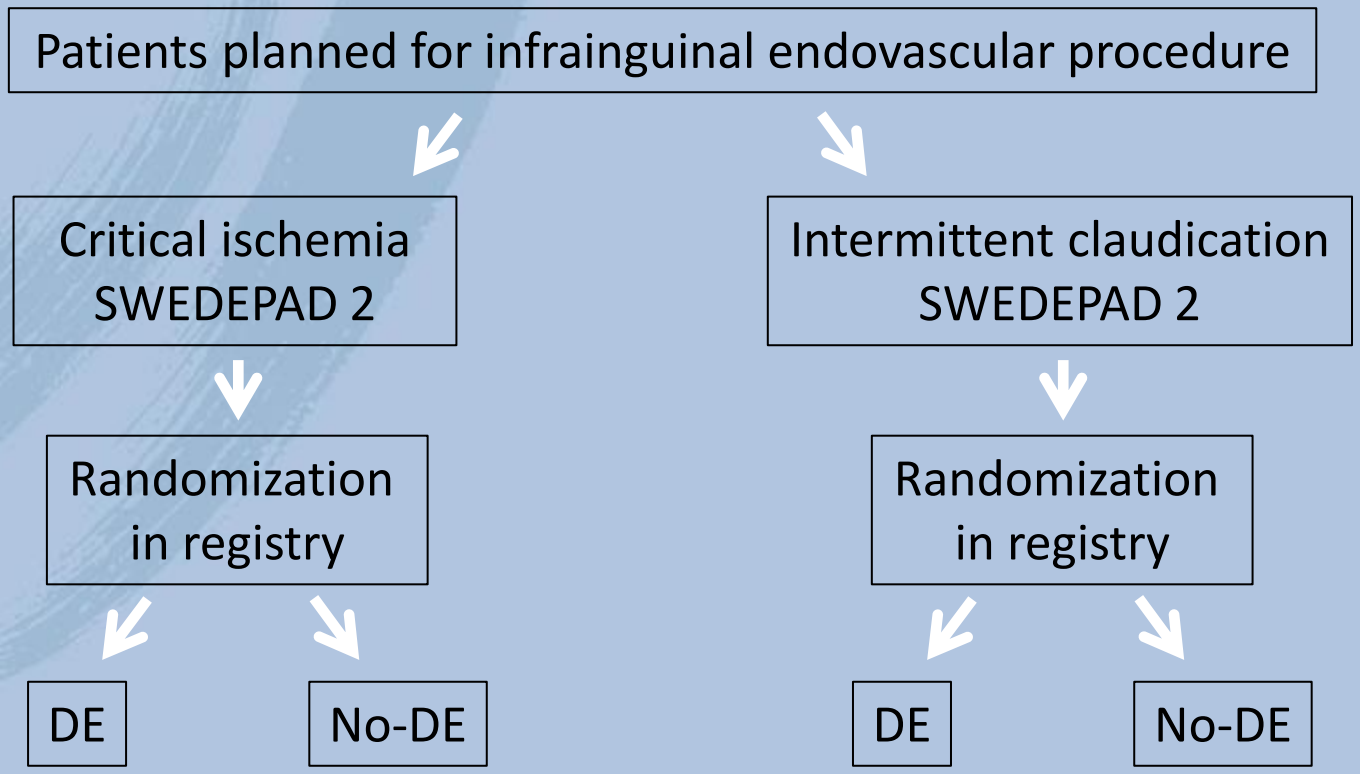
Acute thromboembolic

Infrainguinal aneurysm

Patients planned for infrainguinal endovascular procedure

Critical ischemia
SWEDEPAD 1

Intermittent claudication
SWEDEPAD 2


Patients planned for infrainguinal endovascular procedure
Critical ischemia
SWEDEPAD 2
Intermittent claudication
SWEDEPAD 2
Randomization
in registry
Randomization
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DE
No-DE
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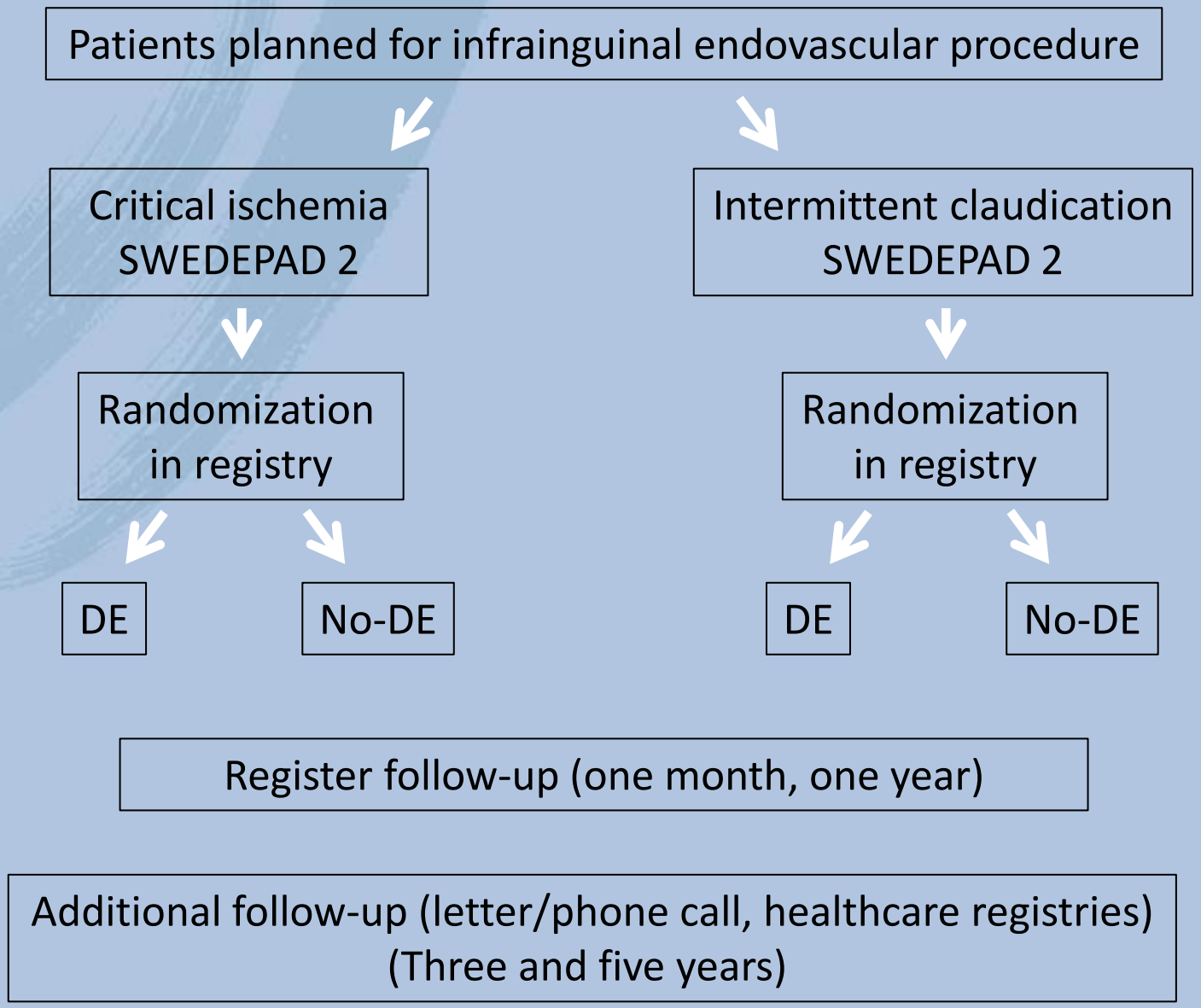
No-DE


Patients planned for infrainguinal endovascular procedure
Critical ischemia SWEDEPAD 2
Intermittent claudication SWEDEPAD 2
Randomization in registry
Randomization in registry
DE
No-DE
DE
No-DE
Register follow-up (one month, one year)
Additional follow-up (letter/phone call, healthcare registries) (Three and five years)

Primary endpoints

Critical Ischemia

- Amputation rate

Intermittent Claudication

- health-related quality of life after one year (VascuQol 6)

Secondary endpoints

Critical Ischemia

- Survival after one year and long-term
- Amputation free survival.
- Freedom from target lesion revascularisation (TLR) after one year.
- Time to target lesion revascularisation (TLR) during follow-up.
- Patency, defined as freedom from binary restenosis, a reduction in lumen diameter ≥50% in patients assessed with duplex ultrasound after one month and after one year.
- Improvement in clinical symptoms, assessed with the Rutherford classification at one month and one year. Particularly changes from Rutherford categories 4, 5 and 6 to lower categories.
- Ankle-brachial index (ABI) after one month and after one year.
- Health related quality of life, assessed with VascuQol-6, a disease-specific health –related quality of life instrument in PAD, after one month and one year, and during long-term follow up.
- Survival after one year and during long-term follow-up.
- Health-economic assessment after one year and during long-term follow-up (only certain centres).

Intermittent Claudication

- Survival after one year and long-term
- Amputation free survival.
- Freedom from target lesion revascularisation (TLR) after one year.
- Time to target lesion revascularisation (TLR) during follow-up.
- Patency defined as freedom from binary restenosis, a reduction in lumen diameter ≥50% in patients assessed with duplex ultrasound after one month and after one year.
- Improvement in clinical symptoms, assessed with the Rutherford classification at one month and one year. Particularly changes from Rutherford categories 2 and 3 to other categories.
- Ankle-brachial index (ABI) after one month and after one year.
- Amputation rate during follow-up, analysed when all patients have been followed for at least one year.
- Health-economic assessment after one year and during long-term follow-up (only certain centres).

Patient numbers

Critical Ischemia

- 2400

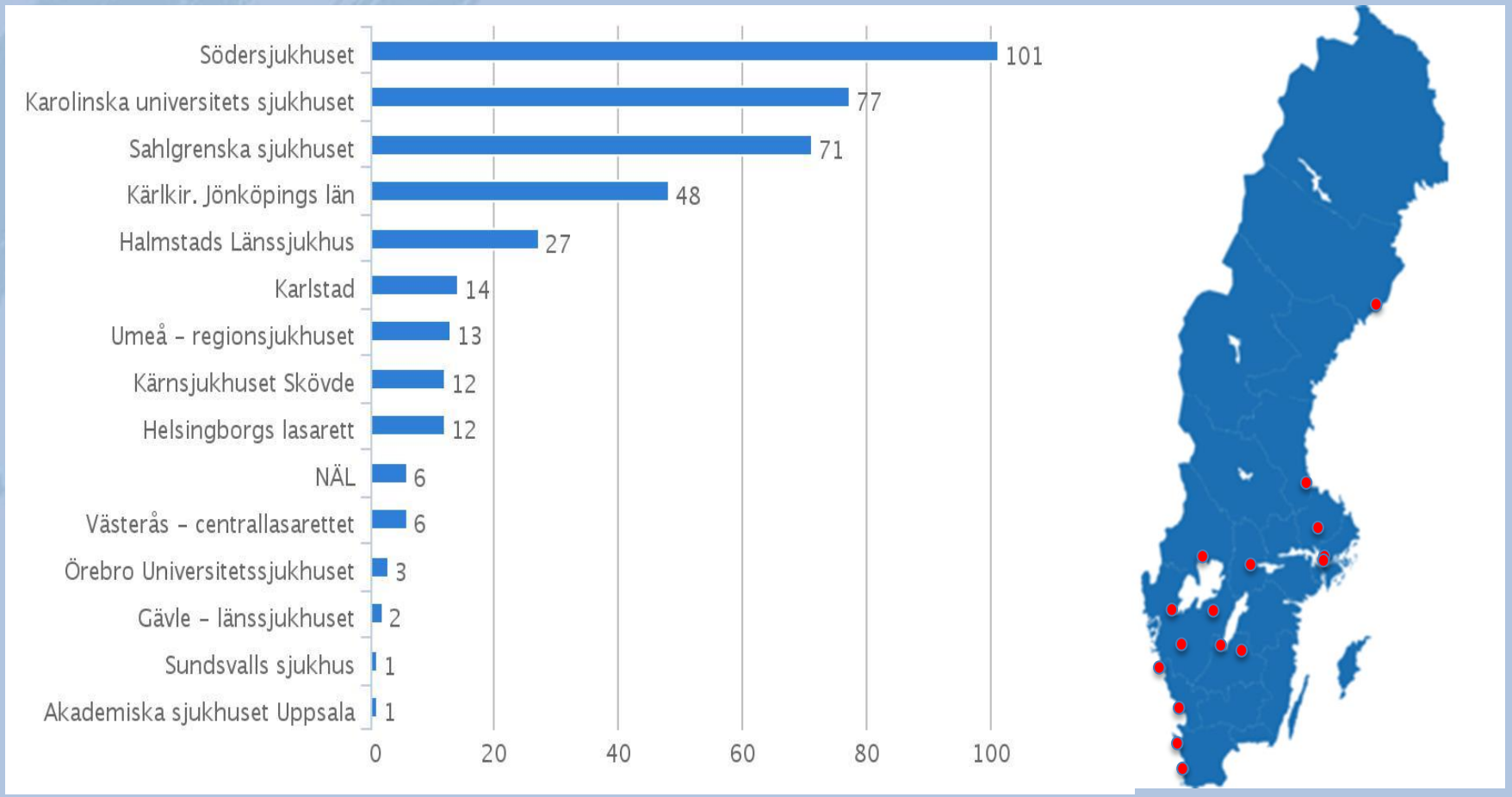
Intermittent Claudication

- 1330

Randomised patients in SWEDEPAD 16-01-24

Total **394**

SWEDEPAD 1	254
SWEDEPAD 2	140



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