Results from the Endovascular Revascularization And Supervised Exercise for claudication study

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DEPARTMENT OF RADIOLOGY AND EPIDEMIOLOGY

- Intermittent claudication
  - Symptomatic form of peripheral arterial disease, 20-40 million cases worldwide
- Functional- and quality of life limitations
- Supervised exercise therapy first-line treatment, endovascular revascularization increasingly performed
- Combination therapy of endovascular revascularization and exercise promising, not investigated in a large randomized trial

Study Objective

ERASE Trial

To compare the clinical effectiveness of Endovascular Revascularization (EVR) plus Supervised Exercise Therapy (SET) versus the standard care of SET only in patients with intermittent claudication.

Study Population

- Stable (>3 months) intermittent claudication
- Vascular obstruction (> 50%) aortoiliac and/or femoropopliteal level
- Target lesion suitable for endovascular revascularization
- No limited ambulation due to any other condition
- No prior treatment (including exercise therapy)

Outcome measures

Primary Endpoint

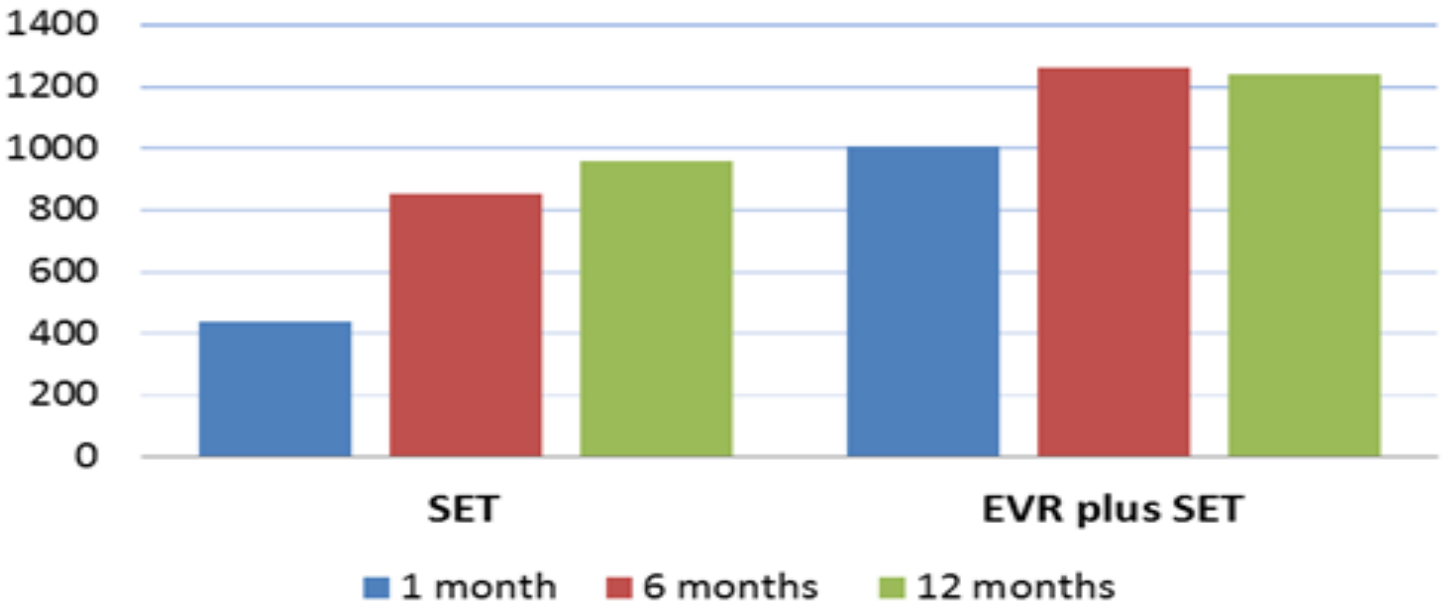
- Maximum walking distance, graded treadmill test (Gardner protocol, 30-min)

Secondary Endpoints

- Pain-free walking distance
- Ankle brachial index at rest and post treadmill walking
- Self-reported quality-of-life scores VascuQol, SF-36, Rating score and EuroQol
- Leg amputations and secondary interventions (revascularizations)

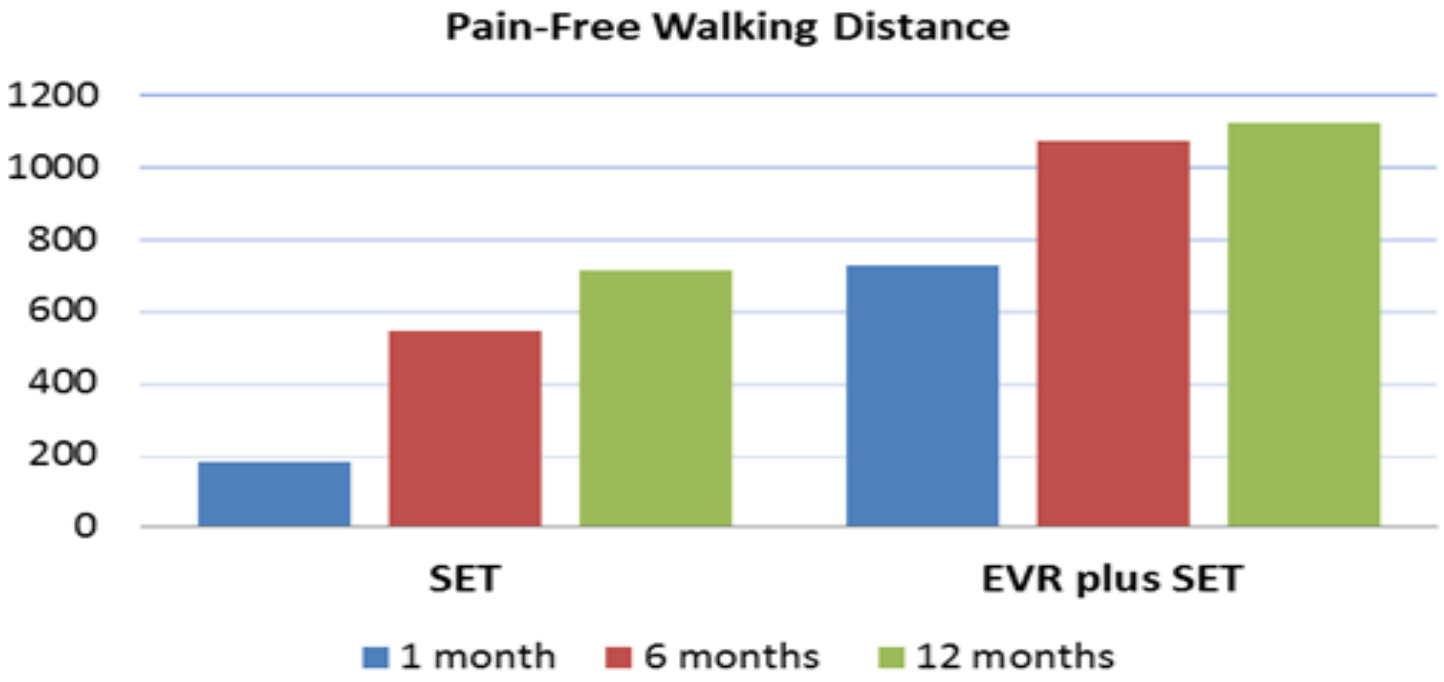
Baseline characteristics of the randomized patients

	SET (n= 106)	EVR+SET (n= 106)
Age (years)	66 (± 10)	64 (± 9)
Gender (Male)	67%	58%
Smoking (Current/Former)	92%	93%
Hypertension	63%	60%
Diabetes	26%	16%
BMI	26.2 (± 4.3)	27.0 (± 4.1)
Dominant Lesion		
Aortoiliac	51%	55%
Femoropopliteal	49%	45%



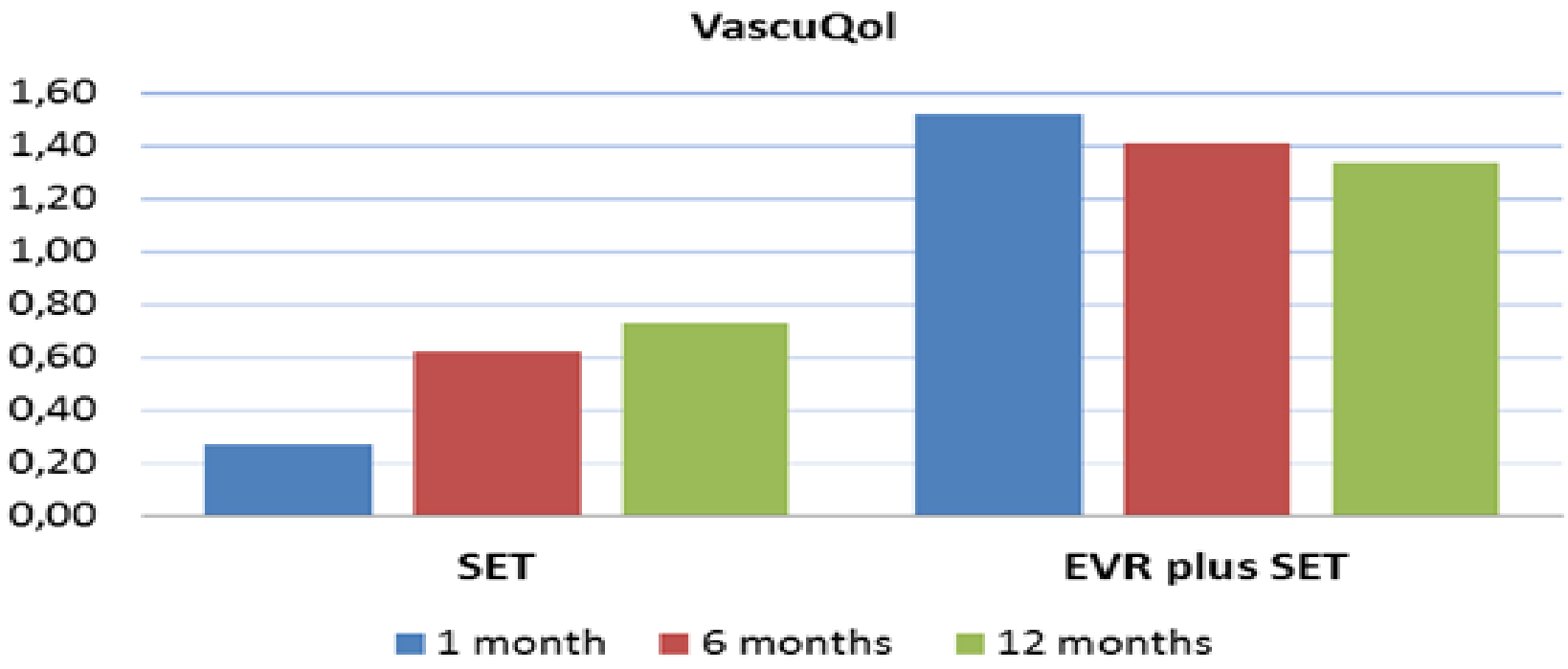
	Mean Difference EVR *plus* SET vs. SET	*P-value*
1 month	566 (358 ; 774)	<0.001
6 months	409 (183 ; 436)	<0.001
12 months	282 (60 ; 505)	0.001

Fig. 1 Bars represent mean change (meters) compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



	Mean Difference EVR *plus* SET vs. SET	*P-value*
1 month	543 (340 ; 744)	<0.001
6 months	529 (315 ; 743)	<0.001
12 months	408 (195 ; 622)	<0.001

Fig. 2 Bars represent mean change (meters) compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization



	Mean Difference EVR *plus* SET vs. SET	*P-value*
1 month	1.25 (0.94 ; 1.56)	<0.001
6 months	0.79 (0.45 ; 1.13)	<0.001
12 months	0.62 (0.20 ; 1.03)	<0.001

Fig. 5 Bars represent mean change compared to baseline; mean (99% CI); SET, supervised exercise therapy; EVR, endovascular revascularization

Summary

- In patients with intermittent claudication a combination therapy of endovascular revascularization followed by supervised exercise therapy resulted in significant greater improvements in functional performance and quality-of-life compared to the standard care of supervised exercise therapy only.

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