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VASCULAR THERAPIES

2017

Richard DeMasi
MD
4/21/17

Supervised Exercise Improves Claudication: Everyone Needs A Fitbit

NO DISCLOSURES

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About the Product

- PurePulse continuous, automatic wrist-based heart rate tracking to better measure calorie burn all day
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by Juboury

318 customer reviews | 299 answered questions

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- Silent Alarm: Wake you up by vibration without disturbing others, Sedentary Remind: Remind you the time to drink, the time to exercise, the time to sleep etc, Standby Time: 7 days long working time
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Treating blocked leg arteries

When you need a procedure—and when you don't

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Five Things Physicians and Patients Should Question

1 Don't do work up for clotting disorder (order hypercoagulable testing) for patients who develop first episode of deep vein thrombosis (DVT) in the setting of a known cause.

Lab tests to look for a clotting disorder will not alter treatment of a venous blood clot, even if an abnormality is found. DVT is a very common disorder, and recent discoveries of clotting abnormalities have led to increased testing without proven benefit.

2 Don't reimage DVT in the absence of a clinical change.

Repeat ultrasound images to evaluate "response" of venous clot to therapy does not alter treatment.

3 Avoid cardiovascular testing for patients undergoing low-risk surgery.

Pre-operative stress testing do[illegible] therapy or decision-making in patients facing [illegible] surgery.

4 Refrain from percutaneous or surgical revascularization of peripheral artery stenosis in patients without claudication or critical limb ischemia.

Patients without symptoms will not benefit from attempts to improve circulation. No evidence exists to support improving circulation to prevent progression of disease. There is no proven preventive benefit, only symptomatic benefit.

5 Don't screen for renal artery stenosis in patients without resistant hypertension and with normal renal function, even if known atherosclerosis is present.

Performing surgery or angioplasty to improve circulation to the kidneys has no proven preventive benefit, and shouldn't be considered unless there is evidence of symptoms, such as elevated blood pressure or decreased renal function.

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Society for Vascular Surgery

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SOCIETY *for* VASCULAR SURGERY

Five Things Physicians and Patients Should Question

4

Don't use interventions (including surgical bypass, angiogram, angioplasty or stent) as a first line of treatment for most patients with intermittent claudication.

A trial of smoking cessation, risk factor modification, diet and exercise, as well as pharmacologic treatment should be attempted before any procedures. When indicated, the type of intervention (surgery or angioplasty) depends on several factors.

Intermittent claudication can vary due to several factors. The life-time incidence of amputation in a patient with claudication is less than 5% with appropriate risk factor modification.

Procedures for claudication are usually not limb-saving, but, rather, lifestyle-improving. However, interventions are not without risks, including worsening the patient's perfusion, and should be reserved until a trial of conservative management has been attempted. Many people will actually realize an increase in their walking distance and pain threshold with exercise therapy. In cases where the claudication limits a person's ability to carry out normal daily functions, it is appropriate to intervene.

Depending upon the characteristics of the occlusive process, and patient comorbidities, the best option for treatment may be either surgical or endovascular.

LEGS

Chronic Arterial Insufficiency

- Asymptomatic → Claudication →

Rest Pain → Ulcer →

Gangrene

SYMPTOMS OF PAD

- Claudication: Dull cramping or pain in muscles of hips, thighs or calf muscles when walking, climbing stairs, or exercise which is relieved with cessation of activity

- Consistent distances but can vary depending upon work load, incline, etc

PHYSIOLOGY OF CLAUDICATION

- Atherosclerosis in peripheral arteries of legs

During exercise, oxygen demand increases

↓

Muscles operate anaerobically

↓

Produce lactic acid and other metabolites

- Lactic acid and other metabolites washed away on rest

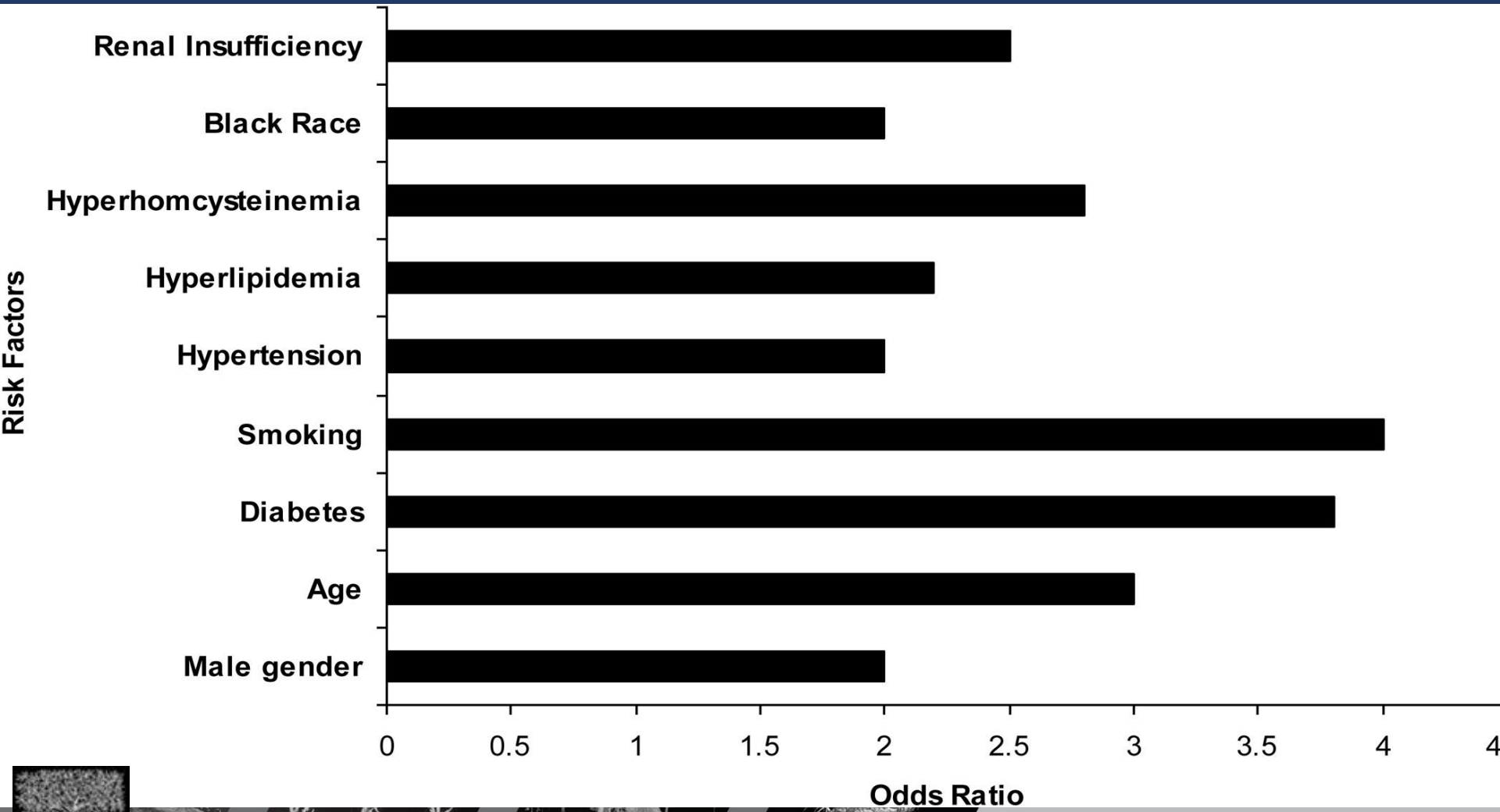
↓

Leg Pain

Angina of the Leg

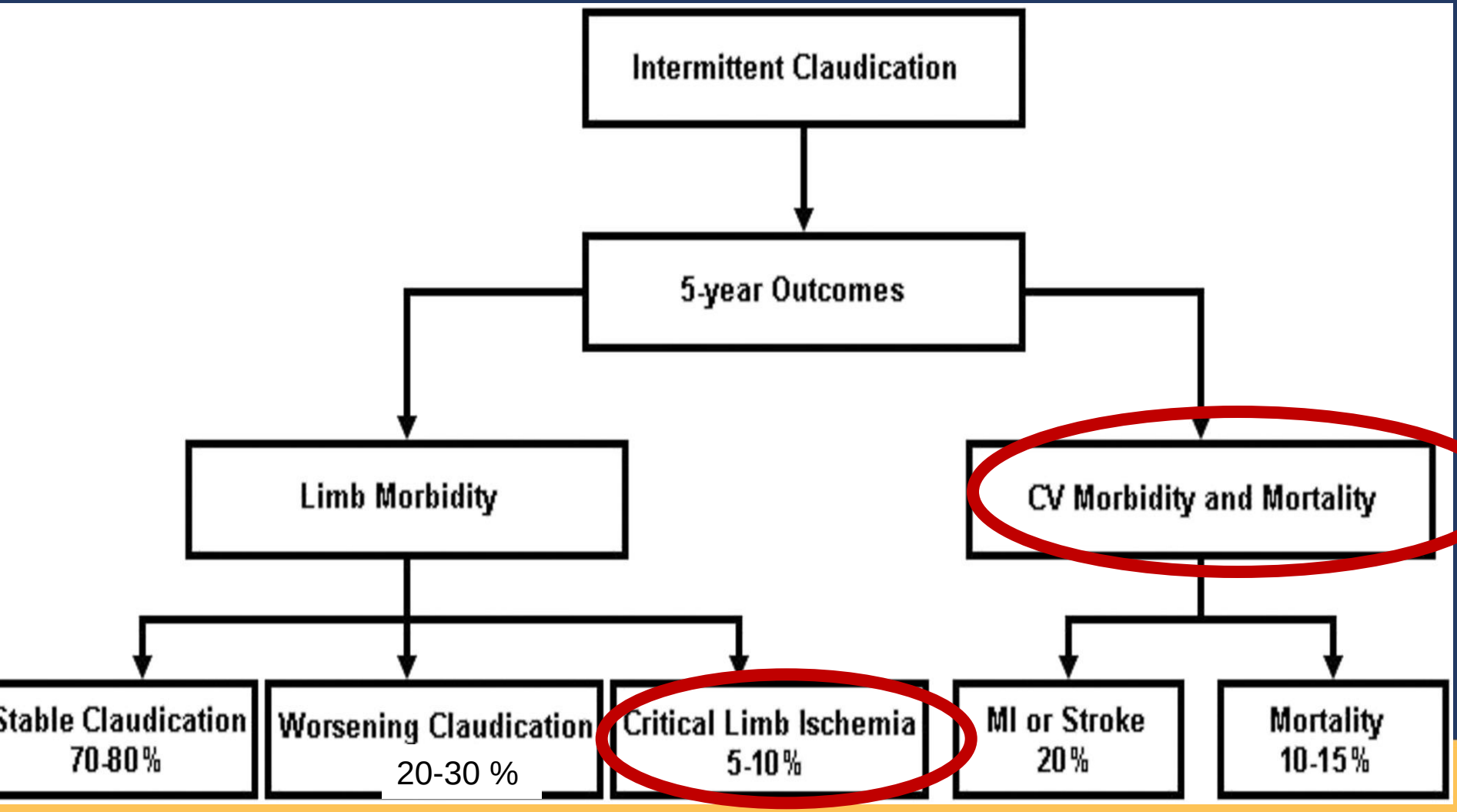
Am J Cardiol 2001; 87 (suppl): 3D-13D

Risk Factors For PAD



Journal of Vascular Surgery 2015 61, 2S-41S.e1DOI: (10.1016/j.jvs.2014.12.009)

Natural History



Journal of Vascular Surgery 2015 61, 2S-41S.e1DOI: (10.1016/j.jvs.2014.12.009)

SYMPTOMS OF PAD

- **Claudication**

Assess Severity

- **How do symptoms impact current lifestyle ?**
- **How would your life be different if your legs were normal ?**

THE ANKLE-BRACHIAL INDEX

$$\text{ABI} = \frac{\text{Lower extremity systolic pressure}}{\text{Brachial artery systolic pressure}}$$

- The Ankle-Brachial Index is 95% sensitive and 99% specific for PAD
- Both ankle and brachial systolic pressures are obtained using a hand-held Doppler instrument

Normal	0.95-1.2
PAD	<0.90
Rest pain/ulceration	<0.40

Source: Peripheral Arterial Disease in People with Diabetes, ADA, Consensus Statement, Diabetes Care, Volume 26, Number 12, December 2003

Use Exercise testing to confirm and quantify severity of PAD in patients with claudication

Mild	can walk 5 mins on a treadmill
Moderate	less than 5 mins
Severe	less than 2 mins on treadmill

RESULTS OF EXERCISE TESTING

MAXIMUM WALK LOAD 3 MIN 0 SEC

2 MPH 12 % GRADE

INITIAL CLAUDICATION 0 MIN 45 SEC

LOCATION bilat hips & buttocks

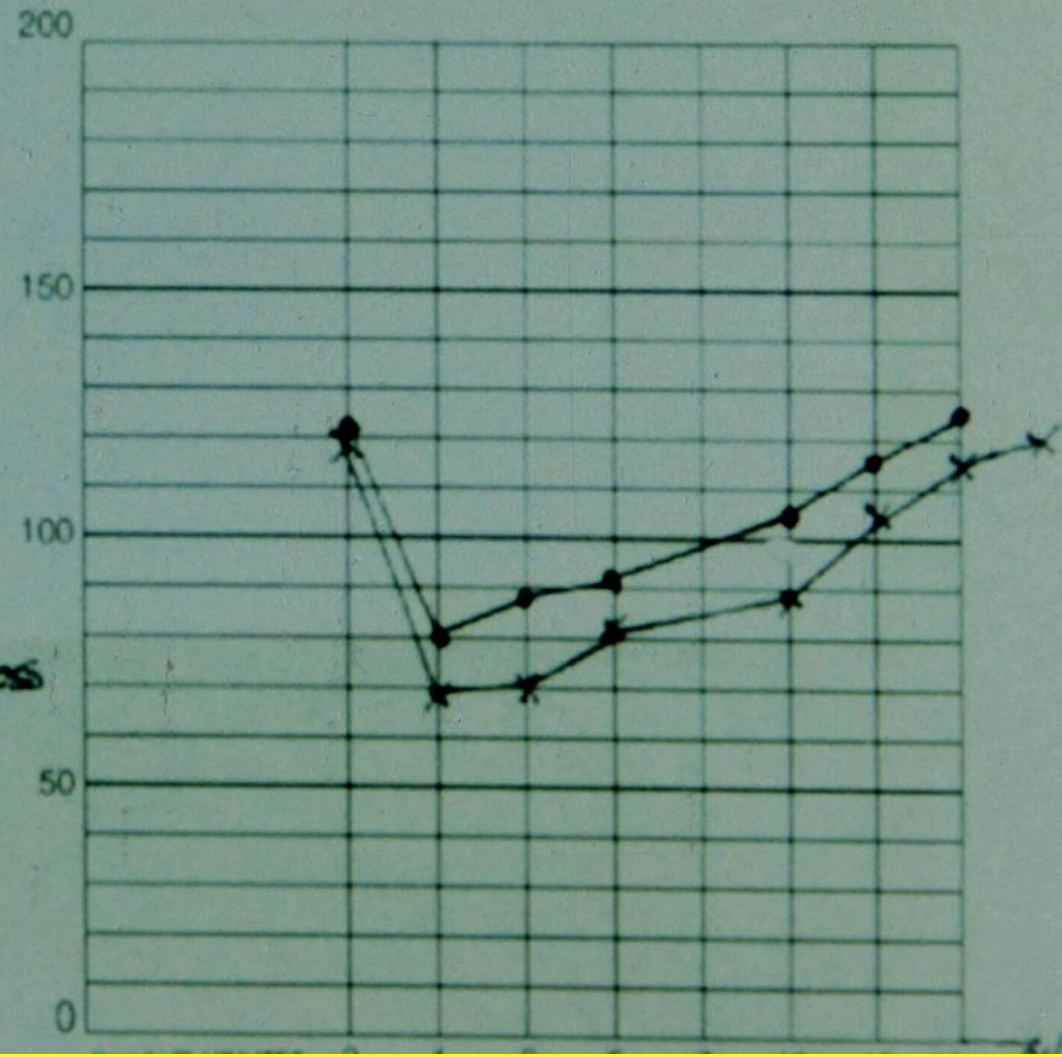
EXERCISE COMMENTS after 2 min of exercise both feet very blanched - white

STOPPED DUE TO dragging (b) leg & numbness

% OF ANKLE SYSTOLIC PRESSURE DROP 1 MINUTE

POST EXERCISE COMPLETION

RIGHT ↓ 34 % LEFT ↓ 43 %



- Does Supervised Exercise Work?

Supervised walking therapy (SWT) in patients with intermittent claudication

Farzin Fakhry, MSc, Koen M. van de Luijtgaarden, MD, Leon Bax, PhD, P. Ted den Hoed, MD, PhD, M.G. Myriam Hunink, MD, PhD, Ellen V. Rouwet, MD, PhD, Sandra Spronk, PhD

Journal of Vascular Surgery
Volume 56, Issue 4, Pages 1132-1142 (October 2012)
DOI: 10.1016/j.jvs.2012.04.046

Results:

Twenty-five RCTs (1054 patients) comparing SWT vs non-interventional observation showed a weighted mean difference of :

180 meters (95% confidence interval, 130-230 meters) in Max WD and

128 meters (95% confidence interval, 92-165 meters) in Pain FreeWD, both in favor of the SWT group.

Journal of Vascular Surgery 2012 56, 1132-1142DOI: (10.1016/j.jvs.2012.04.046

Conclusions:

- SWT is effective in improving MWD and PFWD in patients with IC.

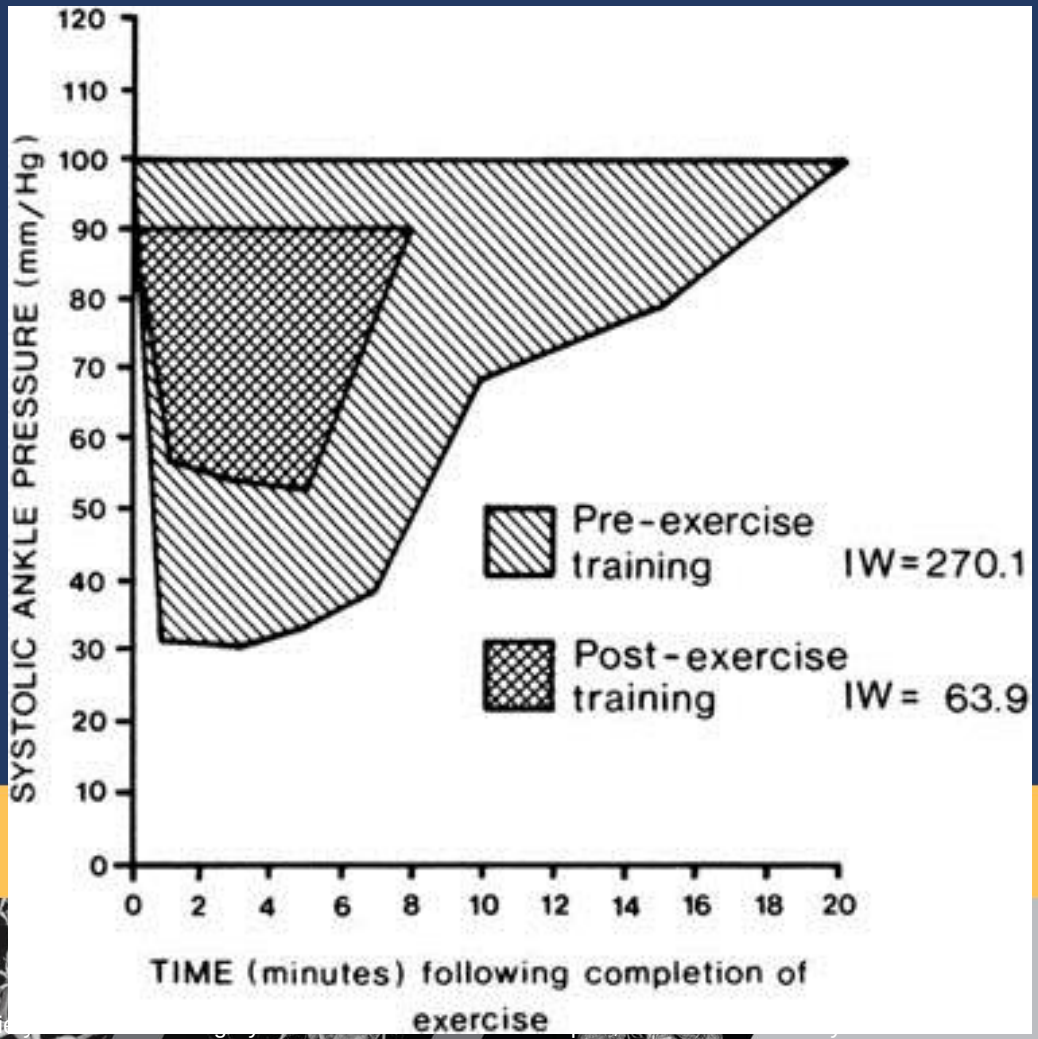
Journal of Vascular Surgery 2012 56, 1132-1142DOI: (10.1016/j.jvs.2012.04.046)

How Does Supervised Exercise Work ?

- No increase in measured ABI
- No increase in blood flow
- Training Effect

The ischemic window: A method for the objective quantitation of the training effect in exercise therapy for intermittent claudication

Richard L. Feinberg, MD, Roger T. Gregory, MD, Jock R. Wheeler, MD, Stanley O. Snyder, MD, Robert G. Gayle, MD, F.Noel Parent, MD, Robert B. Patterson, MD



A systematic review of treatment of intermittent claudication in the lower extremities

Rafael D. Malgor, MD, Fares Alalahdab, MD, Tarig A. Elraiyah, MBBS, Adnan Z. Rizvi, MD, Melanie A. Lane, BA, Larry J. Prokop, MLS, Olivia J. Phung, PharmD, Wigdan Farah, MBBS, Victor M. Montori, MD, MSc, Michael S. Conte, MD, Mohammad Hassan Murad, MD, MPH

Journal of Vascular Surgery
Volume 61, Issue 3, Pages 54S-73S (March 2015)
DOI: 10.1016/j.jvs.2014.12.007

8 systematic reviews and 12 trials enrolling > 1500 Patients

Malgor et al, JVS 3/2015

Intervention	comparison	Outcomes	QOE
SET	Medical management	SET has better walking performance	⊕⊕⊕⊕
Revascularization (open or EVT)	Medical management	Revascularization has better Walking performance & Blood flow parameters	⊕⊕⊕⊕
Revascularization (open or EVT)	SET	Revascularization has better & faster improvement in blood flow parameters	⊕⊕OO
EVT	Open surgery	EVT has lower LOS & complications but less durability	⊕⊕⊕O
Revascularization (open or EVT) + SET	Revascularization alone or SET alone	Combination has better Walking performance & Blood flow parameters	⊕⊕⊕O

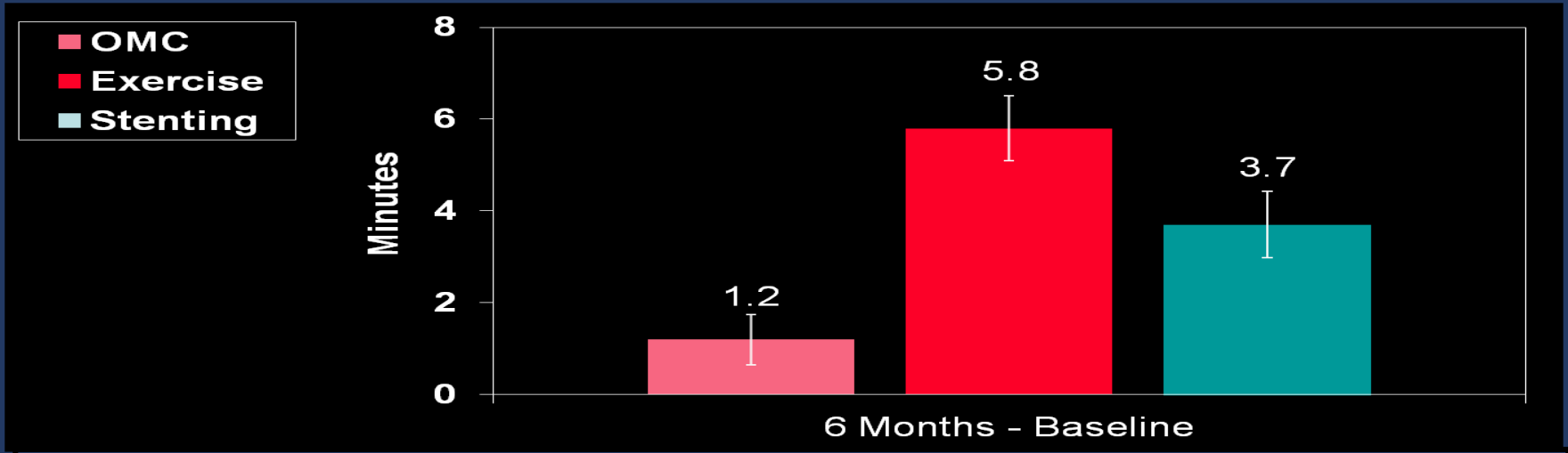
Journal of Vascular Surgery 2015 61, 54S-73SDOI: (10.1016/j.jvs.2014.12.007)

- CLaudication: Exercise Vs. Endoluminal Revascularization
- Prospective multicenter randomized clinical trial that evaluated the relative efficacy and safety of stenting plus optimal medical therapy versus supervised exercise training plus optimal medical therapy versus optimal medical therapy alone in patients with aortoiliac disease.

Cilostazol in all groups

PRIMARY ENDPOINT: PEAK WALKING TIME

Change from Baseline to Six (6) Months



Pair-Wise Comparisons		
	Difference (minutes)	P Value
Exercise vs. OMC	4.6	<0.001
Stenting vs. OMC	2.5	0.02
Exercise vs. Stenting	2.1	0.04

18 MONTH OUTCOMES

Treadmill Walking Time

	OMC (n=15)	SE (n=32)	ST (n=32)	p value
PWT (min)				
Baseline	5.7 (2.6)	5.6 (2.4)	5.2 (2.1)	SE vs. OMC p<.001
18 months	5.9 (2.9)	10.6 (5.7)	8.4 (5.6)	ST vs. OMC p=.04
Change	0.2 (2.1)	5.0 (5.4)	3.2 (4.7)	SE vs. ST p=.16

Murphy, et al., JACC, 2015

CLEVER CONCLUSIONS

- Supervised exercise offers better treadmill walking performance outcomes than stent revascularization.
- Both supervised exercise and stenting are more effective at increasing walking distance compared to pharmacotherapy alone.
- 18 month follow-up data demonstrated that both SE and ST were durable and there was little difference between groups in walking outcomes.
- Cost-effectiveness analysis - if ST is reimbursed by CMS SE should also be reimbursed

Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication

Michael S. Conte, MD, Frank B. Pomposelli, MD, Daniel G. Clair, MD, Patrick J. Geraghty, MD, James F. McKinsey, MD, Joseph L. Mills, MD, Gregory L. Moneta, MD, M. Hassan Murad, MD, Richard J. Powell, MD, Amy B. Reed, MD, Andres Schanzer, MD, Anton N. Sidawy, MD, MPH

Journal of Vascular Surgery
Volume 61, Issue 3, Pages 2S-41S.e1 (March 2015)
DOI: 10.1016/j.jvs.2014.12.009

SVS RECS

Recommendations: Exercise therapy

		Grade	*Level of eviden*
4.12.	We recommend as first-line therapy a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks to all suitable patients with IC.	1	A
4.13.	We recommend home-based exercise, with a goal of at least 30 minutes of walking three to five times per week when a supervised exercise program is unavailable or for long-term benefit after a supervised exercise program is completed.	1	B
4.14.	In patients who have undergone revascularization therapy for IC, we recommend exercise (either supervised or home based) for adjunctive functional benefits.	1	B
4.15.	We recommend that patients with IC be followed up annually to assess compliance with lifestyle measures (smoking cessation, exercise) and medical therapies as well as to determine if there is evidence of progression in symptoms or signs of PAD. Yearly ABI testing may be of value to provide objective evidence of disease progression.	1	C

SVS RECS

Recommendations: General considerations on invasive treatment for intermittent claudication (*IC*)

		Grade	*Level of evidence*
5.1.	We recommend EVT or surgical treatment of IC for patients with significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks.	1	B
5.2.	We recommend an individualized approach to select an invasive treatment for IC. The modality offered should provide a reasonable likelihood of sustained benefit to the patient (>50% likelihood of clinical efficacy for at least 2 years). For revascularization, anatomic patency (freedom from hemodynamically significant restenosis) is considered a prerequisite for sustained efficacy.	1	C

EVT, Endovascular therapy.

vascularnews

Smartphone over treadmill: Mapping claudication with Google Maps

17th March 2017 272

Prasad Jetty

The use of GPS mapping tools has become a cornerstone of modern life. A study published by the *Journal of Vascular Surgery* has demonstrated the clinical opportunities offered by this revolutionary

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Intact Vascular completes enrolment in TOBA II clinical trial

23rd March 2017

VeClose trial indicates 24-month non-inferiority of VenaSeal versus radiofrequency ablation

24th January 2017

GOOGLE MAP

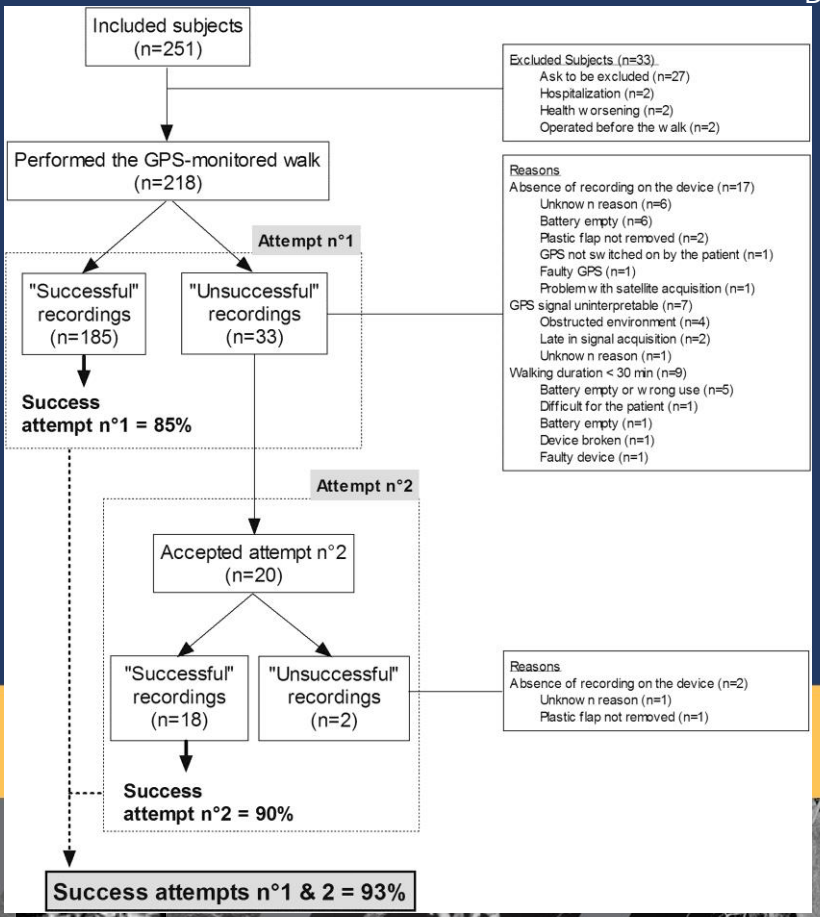
- Results:
  - Fifteen patients were recruited for the study. Determination of walking distances using Google Maps proved to be more accurate than by both clinical history and WIQ, correlating highly with the gold standard of treadmill testing for both claudication onset (r . .805; P < .001) and MWD (r . .928; P < .0001). In addition, distances were generally underreported on history and WIQ..
  - Conclusions: For vascular claudicants with no other walking limitations, Google Maps is a promising new tool that combines the objective strengths of the treadmill test and incorporates real-world walking environments.
- It offers an accurate, efficient, inexpensive, and readily accessible way to assess walking distances in patients with peripheral vascular disease.

(J Vasc Surg 2017;-:1-6.)

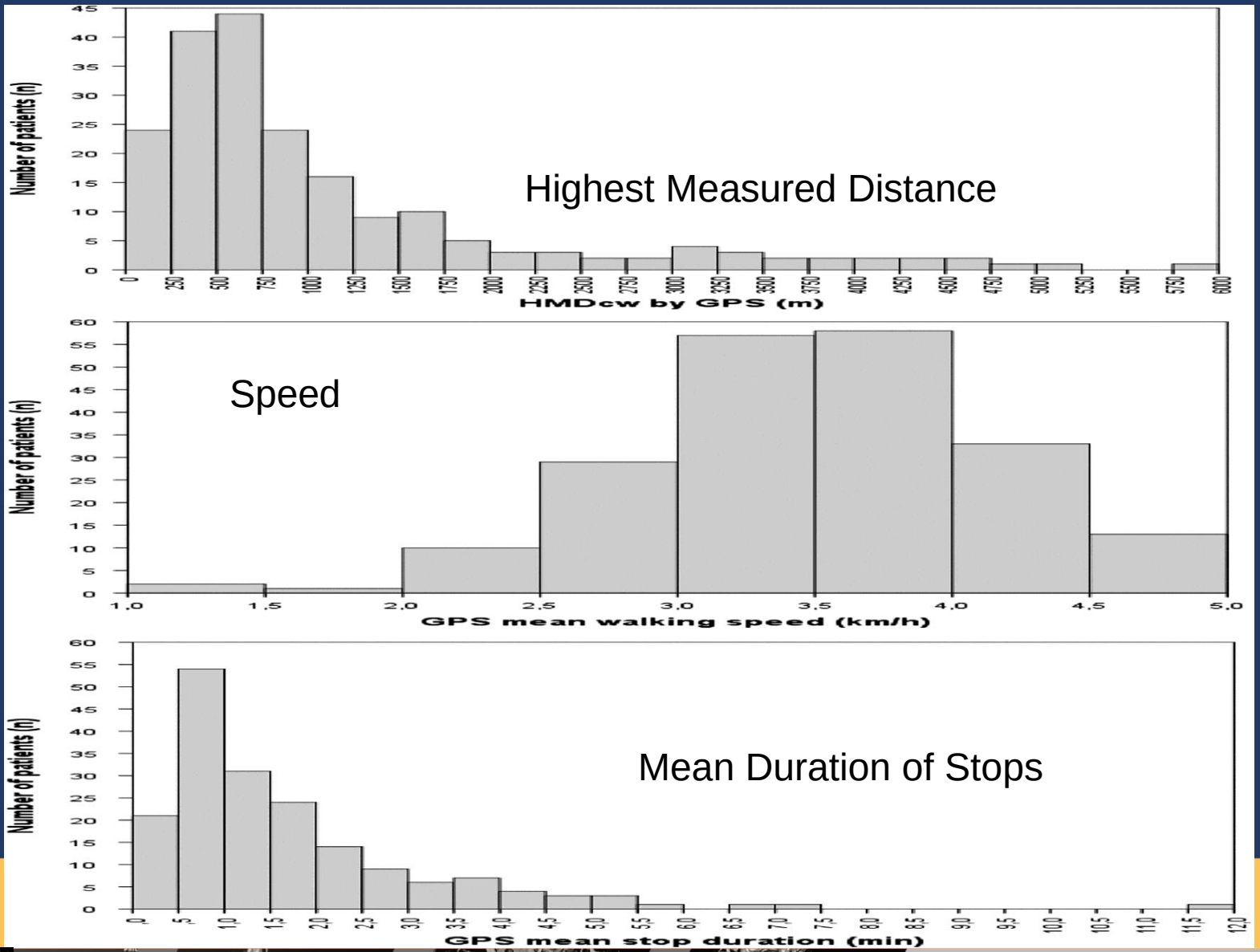
Applicability of global positioning system for the assessment of walking ability in patients with arterial claudication

Marie Gernigon, MS, Alexis Le Faucheur, PhD, Bénédicte Noury-Desvaux, PhD, Guillaume Mahe, MD, PhD, Pierre Abraham, MD, PhD

Journal of Vascular Surgery
Volume 60, Issue 4, Pages 973-981.e1 (October 2014)
DOI: 10.1016/j.jvs.2014.04.053



GPS Study



Journal of Vascular Surgery 2014 60, 973-981.e1DOI: (10.1016/j.jvs.2014.04.053)

GPS Study

- Conclusions:

- GPS is applicable for the non-supervised multicenter recording of walking ability in the community.

- In the future, it may facilitate objective community-based assessment of walking ability, allow for the adequate monitoring of home-based walking programs, and for the study of new dimensions of walking in PAD patients with intermittent claudication.

Journal of Vascular Surgery 2014 60, 973-981.e1DOI: (10.1016/j.jvs.2014.04.053)

(J Vasc Surg 2014;60:973-81.)

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