Supervised Exercise Therapy for Symptomatic Peripheral Artery Disease Among Medicare Beneficiaries Between 2017 and 2018: Participation Rates and Outcomes

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Peripheral artery disease (PAD) is independently associated with impaired function, an increased risk of mortality, and decreased quality of life. Supervised exercise therapy (SET) reduces symptoms and improves walking performance, and is recommended in consensus guidelines.[1] Historically, lack of reimbursement for SET greatly limited access and utilization.[2] However, in May 2017, the Centers for Medicare & Medicaid Services (CMS) determined that the evidence was sufficient to cover SET for beneficiaries with intermittent claudication. Though this provided remuneration to create new SET programs and expand existing ones, data are scant on the utilization of and outcomes associated with SET since CMS' reimbursement decision. This study aimed to address this lack of data by utilizing Medicare beneficiary data.

The data that support the findings of this study are available from the corresponding author upon reasonable request. The study was approved by the institutional review board of Beth Israel Deaconess Medical Center. Patients with a CPT code for SET or ICD-10-CM code for intermittent claudication required by CMS for SET reimbursement between June 1, 2017 (corresponding with CMS' reimbursement agreement) and December 31, 2018 in the 100% CMS Institutional Outpatient File were included. Baseline characteristics and co-morbidities were obtained via a one-year look back in the MedPAR, Carrier, and Chronic Condition Warehouse files. Outcomes included all-cause death, lower extremity revascularization, and hospitalization for myocardial infarction (MI), congestive heart failure (CHF), or stroke through December 31, 2018.

Patients were divided by the presence or absence of a SET CPT code. Categorical variables were reported as frequencies and proportions and compared with chi-squared or

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Fisher's exact tests, as appropriate. To account for baseline differences between patients, the propensity score for receiving SET was calculated for each patient using all baseline characteristics. Each SET patient was then matched using the propensity score to the three nearest unexposed patients. Cox regression was then used to evaluate the association between SET and outcomes in the matched population. Fine-gray methods were used to account for the competing risk of death for non-death outcomes. All p-values <0.05 were considered significant.

Among 129,699 patients with a diagnosis of intermittent claudication, 1,735 (1.3%) were enrolled in SET during the study period. The median number of SET sessions attended was 16 (interquartile range (IQR) 6 – 28), and 89 patients (5.1%) completed the program (36 sessions). Compared with those not enrolled (n=127,964), SET patients were slightly older (73.6 ± 8.0 years vs. 73.1 ± 9.1 years), more likely to be White (87.2% vs. 84.0%), and less likely to be Black (8.8% vs 10.9%), dually-enrolled in Medicaid (12.7% vs. 22.4%), and female (39.0% vs. 42.5%) (Table). A majority of patients enrolled in SET were from the Midwest (48.1%) and Northeast (16.1%) regions of the United States. Only 9.2% and 12.6% of SET patients were from the South Atlantic and South regions of the United States, respectively. In comparison, patients from the South Atlantic and South regions comprised of 18.2% and 21.1% of the non-SET group, respectively.

SET patients were followed for a median of 153 days (IQR 77–252 days) and non-SET patients were followed for a median of 244 days (IQR 130 – 362 days). The one-year cumulative incidence of endovascular and surgical revascularization were 11.9% and 2.4%, respectively (Table). No patients undergoing SET underwent amputation during the follow-up period. In the matched cohort analysis (n = 6,940 patients), the use of endovascular or surgical revascularization was significantly lower among those who underwent SET (endovascular: HR 0.49, 95% CI 0.40–0.60, p<0.001; surgical: HR 0.27, 95% CI 0.18–0.42, p<0.001). There were no other differences in outcomes between groups (Table).

In this study of Medicare beneficiaries with symptomatic PAD, we found very low utilization of SET during the first 19 months after approval by CMS despite a Class IA guideline endorsement.[1] In fact, the referral rate was similar to data from the PORTRAIT registry that preceded reimbursement approval.[3] Patients referred to SET differed in race, sex, socioeconomic status and geographic region compared with those unenrolled, suggesting disparities emerging early during implementation. Participation in SET once enrolled was limited, with few patients completing the full program.

These data highlight the greater effort that is needed to increase SET enrollment across the United States, as well as to improve adherence once enrolled. Strategies to accomplish this may include: greater efforts to educate both providers and patients of the benefits of SET, investment in broadening the regional availability and total number of SET programs, and consideration of novel extensions of SET (via telerehabilitation, for example). Overall, a multifaceted approach will be needed to dramatically increase utilization. Furthermore, there needs to be a focus on ensuring that all patients with PAD, irrespective of race, geographic region, or socioeconomic status, have access to this guideline-recommended treatment.

Limitations of this study include: the small number of patients referred to SET, the low event rates and the short follow-up time, the possibility of treatment selection bias and residual confounding, the inability to assess severity of symptoms due to the use of claims codes, and the lack of detail regarding SET protocols.

Funding:

References

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Table.
Patient Characteristics and Outcomes Stratified by SET Referral.

Characteristics of and one-year cumulative incidences in all SET versus non-SET patients and the propensity score matched cohorts.

Characteristics	SET (n=1,735)	Non-SET (n=127,964)	p-value		SET (n=1,735)	Non-SET Matched Cohort (n=5,205)	p-value
Age (y), mean (SD)	73.6±8.0	73.1±9.1	0.02		73.6±8.0	73.7±8.5	0.84
Dual Medicaid-Medicare enrollment, n (%)	221 (12.7%)	28642 (22.4%)	<0.001		221 (12.7%)	672 (12.9%)	0.85
Female, n(%)	677 (39.0%)	54438 (42.5%)	0.003		677 (39.0%)	2041 (39.2%)	0.89
Race, n (%)			0.002				0.86
White	1512 (87.2%)	107436 (84.0%)			1512 (87.2%)	4560 (87.6%)	
Black	153 (8.8%)	13970 (10.9%)			153 (8.8%)	453 (8.7%)	
Other	13 (0.7%)	1348 (1.1%)			13 (0.7%)	42 (0.8%)	
Asian	5 (0.3%)	1037 (0.8%)			5 (0.3%)	13 (0.2%)	
Hispanic	17 (1%)	1982 (1.5%)			17 (1%)	58 (1.1%)	
Chronic kidney disease	795 (45.8%)	62322 (48.7%)	0.02		795 (45.8%)	2359 (45.3%)	0.72
Congestive heart failure	550 (31.7%)	41322 (32.3%)	0.60		550 (31.7%)	1597 (30.7%)	0.43
Diabetes	821 (47.3%)	63023 (49.3%)	0.11		821 (47.3%)	2495 (47.9%)	0.66
Ischemic heart disease	1211 (69.8%)	88757 (69.4%)	0.70		1211 (69.8%)	3618 (69.5%)	0.82
Stroke/transient ischemic attack	116 (6.7%)	9938 (7.8%)	0.10		116 (6.7%)	333 (6.4%)	0.67
Hyperlipidemia	1366 (78.7%)	101318 (79.2%)	0.65		1366 (78.7%)	4114 (79.0%)	0.79
Hypertension	1494 (86.1%)	113489 (88.7%)	<0.001		1494 (86.1%)	4469 (85.9%)	0.80
Tobacco use	965 (55.6%)	74339 (58.1%)	0.04		965 (55.6%)	2827 (54.3%)	0.34
Total comorbidities, mean (SD)	6.6±3.1	7.1±3.0	<0.001		6.6±3.1	6.4±2.9	0.15
Prior Intervention, n (%)							
Endovascular Revascularization	306 (17.6%)	27657 (21.6%)	<0.001		306 (17.6%)	902 (17.3%)	0.77
Surgical Revascularization	50 (2.9%)	3137 (2.5%)	0.25		50 (2.9%)	139 (2.7%)	0.64
U.S Geographic Region, n (%)			<0.001				0.97
Northeast	270 (16.1%)	22511 (18.2%)			270 (16.1%)	752 (14.4%)	
South Atlantic	155 (9.2%)	22507 (18.2%)			155 (9.2%)	489 (9.4%)	
Midwest	809 (48.1%)	38971 (31.5%)			808 (48.1%)	2477 (47.6%)	
South	211 (12.6%)	26209 (21.1%)			211 (12.6%)	812 (15.6%)	
Mountain	89 (5.3%)	4074 (3.3%)			89 (5.3%)	262 (5%)	
Pacific	144 (8.6%)	9191 (7.4%)			144 (8.6%)	404 (7.8%)	
Outcomes	**SET (n=1,735) One-Year Cumulative Incidence**	**Non-SET (n=127,964) One-Year Cumulative Incidence**	**p-value**		**SET (n=1,735) One-Year Cumulative Incidence**	**Non-SET Matched Cohort (n=5,205) One-**	**p-value**

						Year Cumulative Incidence	
Death	33 (3.5%)	4,367 (4.6%)	0.04		33 (3.5%)	135 (3.5%)	0.73
Endovascular Revascularization	110 (11.9%)	19,042 (16.9%)	<0.001		110 (11.9%)	718 (15.7%)	<0.001
Surgical Revascularization	23 (2.4%)	6,386 (5.9%)	<0.001		23 (2.4%)	280 (6.3%)	<0.001
Admission for Myocardial Infarction	18 (1.6%)	1,746 (2.0%)	0.64		18 (1.6%)	68 (1.9%)	0.54
Admission for Congestive Heart Failure	33 (2.9%)	3,845 (4.4%)	0.28		33 (2.9%)	131 (3.7%)	0.99
Admission for Stroke	4 (0.3%)	798 (0.9%)	0.28		4 (0.3%)	35 (1.1%)	0.30

SD = standard deviation. SET = supervised exercise therapy.