Comparison of Outcomes and Cost of Endovascular Management Versus Surgical Bypass for the Management of Lower Extremities Peripheral Arterial Disease

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The management of lower extremities peripheral arterial disease (LE-PAD) has always been debatable. We sought to explore in-hospital outcomes in hospitalizations that underwent endovascular or bypass surgery for LE-PAD from nation's largest, publicly available database. The National Inpatient Sample from 2012 to 2014 was queried to identify adult hospitalizations underwent endovascular management and bypass surgery for LE-PAD. Appropriate *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnostic and procedural codes were utilized to identify hospitalizations. A total of 89,256 hospitalizations were identified having endovascular management or bypass surgery for LE-PAD. More hospitalizations underwent endovascular intervention as compared with bypass surgery. Overall, hospitalizations for endovascular management had higher baseline co-morbidities and older age. A propensity score matched analysis was performed to compare in-hospital outcomes. After matching, 28,791 hospitalizations were included in each group. In-hospital mortality was significantly lower with endovascular intervention procedure as compared with surgical bypass group (1.5% vs 2.5%, p 0.001). All other secondary outcomes were noted lower with endovascular management except stroke and postprocedural infection. Taken together, these may account for higher discharges to home, lower length of stay, and less cost of hospitalizations associated with endovascular management. In conclusion, endovascular management is associated with lower in-hospital morbidity, mortality, length of stay, and cost when compared with bypass surgery in this study. **(Am J Cardiol 2018;122:1790−1796)**

Lower extremities peripheral arterial disease (LE-PAD) is a significant public health burden as it is associated with significant morbidity and mortality.[1,2] Revascularization is considered as a reasonable approach for the management of lifestyle-limiting claudication that has inadequate response to exercise and pharmacological therapy (class of recommendation IIa and level of evidence A).[3−6] The endovascular management and surgical bypass are recommended for the management of LE-PAD; however, "endovascular first" has been suggested for the majority of the peripheral arterial disease (PAD) patients in recently published ACC/AHA and ESC guidelines.[3,5,7] Till date, only bypass versus angioplasty in severe ischemia of the leg (BASIL) trial compared endovascular therapy to open surgery.[8] It demonstrated no superior benefits with endovascular therapy at 2 years. However, this trial was performed almost a decade back, and remarkable innovations in the field of endovascular management have occurred which led to an increase in the use of endovascular therapy.[6] In this era of recent advancements in endovascular therapy, there is a paucity of data on the management of LE-PAD hospitalizations. The aim of this study was to compare in-hospital outcomes of hospitalizations for endovascular management versus surgical bypass for LE-PAD from the nation's largest database.

Methods

To compare outcomes for hospitalizations that underwent peripheral arterial endovascular management or bypass surgery, this study utilized the Nationwide Inpatient Sample (NIS) database for the calendar years 2012 to 2014.[9] The sampling strategy was changed after 2012 and hence we did not include hospitalizations before 2012.[10] This database has been described previously.[11,12] Briefly, NIS is developed as part of the Healthcare Cost and Utilization Project, sponsored by the Agency for Healthcare Research and Quality. This is the largest publicly available

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all-payer inpatient care database in the United States, and the selected time-frame contains data from 45 states. The NIS data are weighted to represent nearly 95% of all hospital discharges nationally. Institutional review board approval and informed consent were not required for this study as this study includes a de-identified database. The principles underlying the Declaration of Helsinki were adhered to in this study.

This study utilized *International Classification of Disease-Ninth Edition-Clinical Modification* (ICD-9-CM) diagnostic codes for identification of PAD which included primary as well as secondary diagnostic codes. This study defined PAD hospitalizations (n = 1,103,120) using ICD-9-CM diagnosis codes 440.0, 440.2, 440.3, 440.8, 440.9, 444.0, 444.8, 444.9, 447.8, or 447.9. For appropriate procedure identification, this study utilized ICD-9-CM procedure codes for peripheral endovascular intervention procedures (ICD-9-CM procedure codes 00.55, 17.56, 39.50, or 39.90, n = 62,535) or bypass surgery (ICD-9-CM procedure codes 39.25, 39.26, 39.39, n = 36,873) which also included primary and secondary procedure codes. ICD-9-CM codes were selected based on experience from previous studies.[12] Sequential revascularization was defined as both endovascular and surgical revascularization performed during a single hospital admission. Hospitalizations with sequential revascularization were removed from the study (n = 5,017) to avoid overlapping of the procedure related outcomes. All hospitalizations below 18 years of age were excluded from the analysis (n = 118). The final analysis included 89,256 hospitalizations from which 57,428 were included in endovascular management group and 31,828 were included in the surgical bypass group (Figure 1).

In-hospital mortality was the primary outcome in this study. Secondary end points included major amputation, nonmajor amputation, gangrene, infection of the lower limb, blood loss requiring transfusion, and stroke.

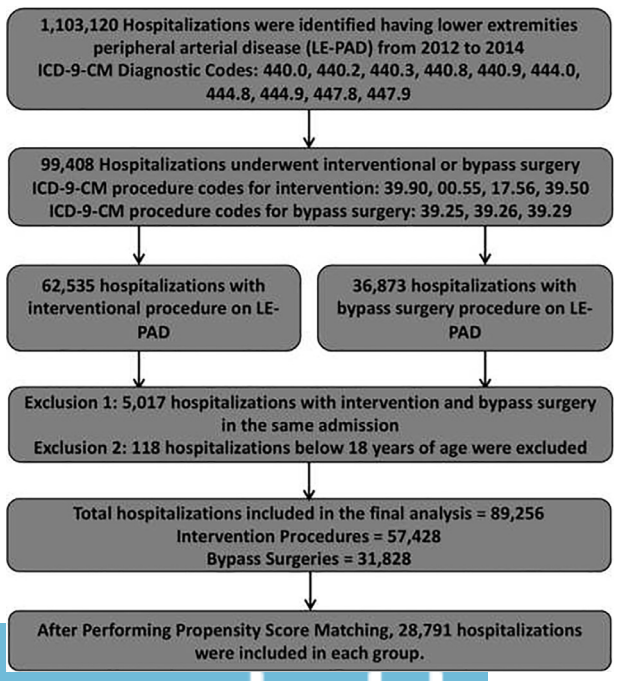

Figure 1. Flowchart for the selection of the study cohorts.

Demographic and clinical characteristics compiled in the NIS were utilized. Age, gender, race, hospital region, teaching status of the hospital, median household income, primary payer, and Elixhauser co-morbidities were compared between the groups. The race was categorized by Caucasians, African-Americans, or others. The type of admission designated as elective and nonelective (emergent or urgent) was compared. Additionally, to analyze the cumulative effect of resource utilization which can be measured in length of hospitalizations stay, disposition, and cost of hospitalization were analyzed for each group. Elixhauser co-morbidities were utilized to identify co-morbidities.[13] Charlson's co-morbidity index (CCI) was analyzed to measure the severity of co-morbid conditions in each group.[13] Details of the ICD-9-CM codes used to identify co-morbidities are available in the Supplementary Table 1 and Supplementary Table 2. The score ranges from 0 to 33, with higher scores corresponding to a greater burden of co-morbid diseases. Hospital covariates included hospital geographic region, rural versus urban, or teaching versus nonteaching hospitals.

The analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, North Carolina). The continuous variables were expressed as a mean ± standard deviation and the categorical variable was expressed as a frequency in percentage. Chi-square test was utilized for categorical data and Student's *t* test for the comparison of continuous data. All tests were considered significant when a p value is below 0.05. This study included multivariate predictors of in-hospital mortality in the overall population including interventions as one of the variables (Supplementary Table 3). Details of the methods and results for this multivariate analysis have been explained in the online Supplementary section. This study included propensity score-matched analysis in those treated with endovascular intervention versus surgical bypass. This is to adjust for baseline differences existed between the groups. First, a logistic regression model was performed that included age, gender, race, CCI, teaching status, hospital region, primary payer, and median household income. After this, matching was performed using one-to-one scheme without replacement using the nearest number matching method. After matching, this study calculated the absolute standardized difference in the groups. Standardized difference below 10% was considered as acceptable in this study as it demonstrates a small difference between 2 groups.[14] Finally, McNemar's test or Wilcoxon-rank-sum test was utilized to compare for primary and secondary outcomes.[15]

Results

During the calendar years 2012 to 2014, and using restrictions outlined in the methods, 89,256 hospitalizations with PAD who underwent either endovascular management or surgical bypass were identified for this analysis. Table 1 contains overall demographic data and baseline characteristics for these hospitalizations. The mean age of hospitalizations with the endovascular procedure and bypass surgery was 68.6 years and 66.2 years, respectively ($p \leq 0.001$). Male admissions were noted higher as compared with females in the 2 groups of this study, 56.4% in

Table 1
Demographics and baseline characteristics: stratified by intervention procedure and bypass surgery (unadjusted analysis)

Variables	Intervention procedure (N = 57,428)	Bypass surgery (N = 31,828)	p Value
Age (years), mean ± standard deviation	68.6 ± 12.2	66.2 ± 12.3	<0.001
Men	32,420 (56.4%)	20,266 (63.7%)	<0.001
Women	25,007 (43.6%)	11,561 (36.3%)	
White	37,413 (65.1%)	22,816 (71.7%)	<0.001
Black	9,111 (15.9%)	4,359 (13.7%)	
Others	10,902 (19%)	4,652 (14.6%)	
Non-elective admissions	33,590 (59%)	9,805 (31%)	<0.001
Charlson/Deyo's co-morbidity index			
0	8,144 (14.2%)	6,343 (19.9%)	<0.001
1	12,820 (22.3%)	9,404 (29.5%)	
2	10,771 (18.8%)	6,652 (20.9%)	
≥ 3	25,693 (44.7%)	9,429 (29.6%)	
Teaching status of the hospital			
Rural	3,116 (5.4%)	1,879 (5.9%)	0.004
Urban, non-teaching	18,478 (32.2%)	10,040 (31.5%)	
Urban, teaching	35,834 (62.4%)	19,909 (62.5%)	
Hospital region			
Northeast	11,300 (19.7%)	5,861 (18.4%)	<0.001
Midwest	13,669 (23.8%)	7,508 (23.6%)	
South	23,665 (41.2%)	13,756 (42.2%)	
West	8,794 (15.3%)	4,703 (14.8%)	
Median household income for patient's ZIP code (Percentile)			
0-25th	18,861 (33.5%)	9,985 (32%)	<0.001
26-50th	15,000 (26.6%)	8,832 (28.3%)	
51-75th	12,682 (22.5%)	7,238 (23.2%)	
76-100th	9,791 (17.4%)	5,175 (16.6%)	
Primary Payer			
Medicare/Medicaid	45,910 (80%)	23,105 (72.6%)	<0.001
Private insurance	8,769 (15.3%)	7,032 (22.1%)	
Other/self-Pay/no-pay	2,727 (4.7%)	1,677 (5.3%)	
Elixhauser co-morbidities			
Diabetes mellitus	14,579 (25.4%)	8,032 (25.2%)	0.62
Hypertension	44,888 (78.2%)	24,758 (77.8%)	0.19
Liver disease	1,077 (1.9%)	532 (1.7%)	0.028
Neurological disorders	3,185 (5.5%)	1,439 (4.5%)	<0.001
Obesity*	6,139 (10.7%)	3,211 (10.1%)	0.005
Smoker	25,655 (44.7%)	18,716 (58.8%)	<0.001
Valvular disease	1,035 (1.8%)	191 (0.6%)	<0.001
Chronic pulmonary disease	14,008 (24.4%)	9,675 (30.4%)	<0.001
Renal failure	18,731 (32.6%)	5,535 (17.4%)	<0.001
Congestive heart failure	3,636 (6.3%)	584 (1.8%)	<0.001
Presentation and procedural detail			
Chronic limb ischemia	12,296 (21.4%)	9,648 (30.3%)	<0.001
Drug eluting stent	1,832 (3.2%)	N/A	N/A
Bare metal stent	27,065 (47.1%)	N/A	N/A
Angioplasty	56,275 (49.7%)	N/A	N/A
Thrombectomy	20 (0.1%)	N/A	N/A
Atherectomy use	10,969 (19.1%)	N/A	N/A

N/A = not available.
* Obesity was defined as a body mass index above 30 kg/m^2.

endovascular intervention group and 63.7% in bypass surgery group (p ≤0.001). The population was predominantly Caucasian with more than 65% hospitalizations in endovascular procedure group, and more than 70% in bypass surgery group. There were less emergent, or urgent admissions observed with bypass surgery as compared with the endovascular procedure group (59% vs 31%, p ≤0.001). The majority of hospitalizations had a significant burden of co-morbidity as suggested by CCI ≥3 with highest in hospitalizations that underwent the endovascular procedure (44.7%) as compared with surgical bypass (29.6%; p ≤0.001). Unadjusted mortality is highest in the age group below 35 years and above 80 years in the groups (Supplementary Figure 1). With increasing co-morbidity burden, in-hospital mortality increased in each group (Figure 2). Finally, women have higher in-hospital mortality as compared with men with the 2 interventions (Figure 2).

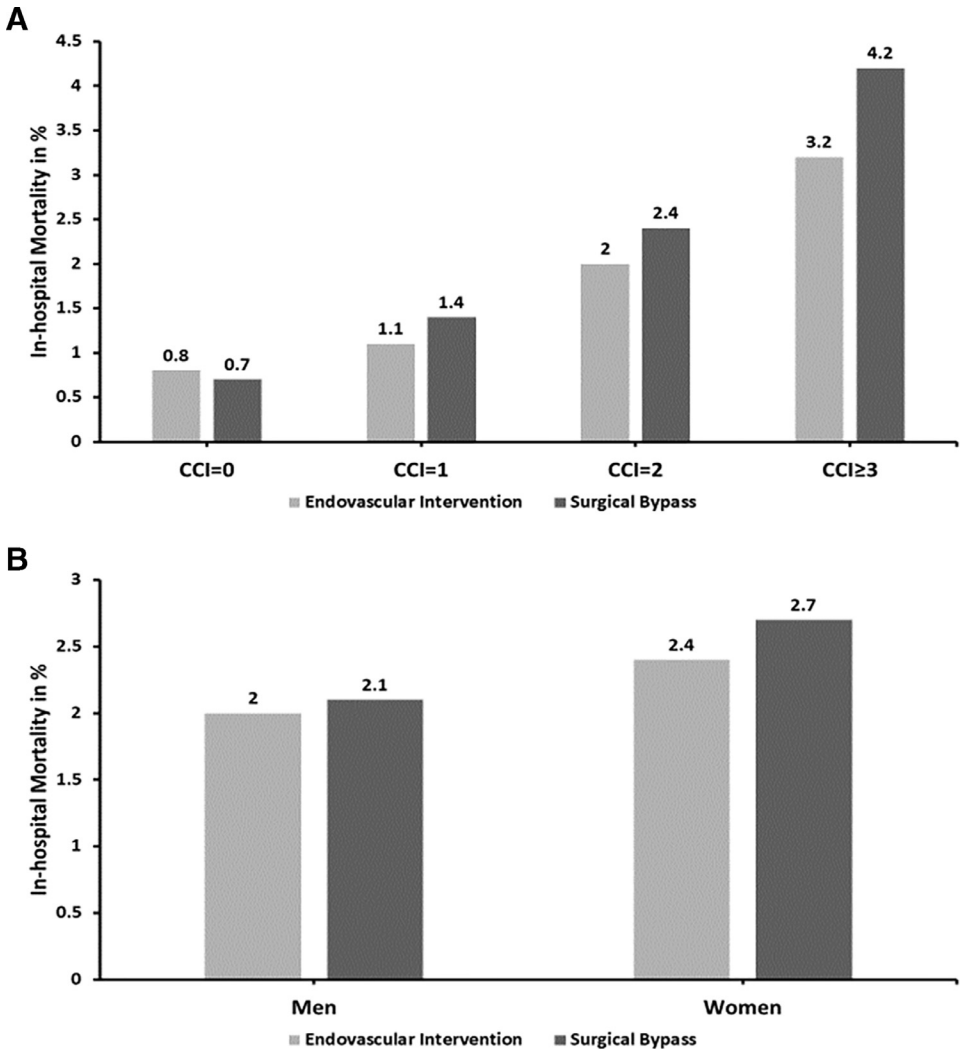

Figure 2. *(A)* In-hospital mortality per Charlson's co-morbidity index. *(B)* The difference in the in-hospital mortality between men and women with the 2 types of procedures. CCI = Charlson's co-morbidity index.

After performing propensity score matching, there was a small difference (<10%) in all variables (Table 2). Each group included 29,436 hospitalizations after performing 1:1 match. Our primary end point, in-hospital mortality was significantly lower with endovascular management as compared with surgical bypass group (1.5% vs 2.5%, $p \leq 0.001$). Secondary outcomes were also noted to be lower with endovascular management including major amputation (1% vs 1.3%, $p \leq 0.001$), nonmajor amputation (4% vs 5.5%, $p \leq 0.001$), gangrene (2.8% vs 3.2%, $p = 0.005$), and acute renal failure (8.9% vs 11.7%, $p \leq 0.001$). Blood loss requiring transfusion was almost double with bypass surgery (11.1% vs 20.6%, $p \leq 0.001$), while stroke rates were comparable in the groups (0.7% vs 0.8%, $p = 0.42$). In contrast, postprocedure infection rates were higher with endovascular procedures (8.3% vs 6.4%, $p \leq 0.001$; Table 3).

In the PAD hospitalizations treated with endovascular interventions, 66.4% of hospitalizations were discharged to home and their median length of in-hospital stay was 3 days, while after surgical bypass about half of the hospitalizations (49.2%) were sent to the home and their median length of hospital stay was 5 days ($p \leq 0.001$ for both). This translated to a higher cost of hospitalization with surgical bypass as compared with endovascular management (25,430$ vs 26,271$, $p \leq 0.001$; Table 3).

Discussion

In this large, retrospective study, we reported "real-world" comparison of endovascular management versus surgical bypass for the management of LE-PAD. We observed almost double hospitalizations for endovascular therapy as compared with surgical bypass. Hospitalizations for endovascular management had older age and higher baseline co-morbidities. Hypertension and smoking were the most common co-morbidities noticed in the 2 groups. In propensity-adjusted hospitalizations, endovascular management was associated with lower in-hospital mortality and morbidities except for stroke and postoperative infection. This may have translated to the shorter length of stay and less cost of hospitalizations in these cohorts. Finally, more hospitalizations were discharged to home after endovascular management. This is the largest study till date

Table 2
Baseline characteristics in propensity score-matched cohorts (1:1): stratified by intervention procedure and bypass surgery

Variables	Intervention procedure (N = 28,791)	Bypass surgery (N = 28,791)	Standardized difference in %
Age (years), mean ± standard deviation	67.3 ± 11.8	67.0 ± 11.1	2.2
Women	10,710 (37.2%)	10,912 (37.9%)	1.6
White	20,672 (71.8%)	20,355 (70.7%)	2.4
Black	3,829 (13.3%)	3,973 (13.8%)	
Others	4,290 (14.9%)	4,462 (15.5%)	
Non-elective admissions	9,760 (33.9%)	9,789 (34%)	0.2
Charlson/Deyo's co-morbidity index			
0	5,499 (19.1%)	5,096 (17.7%)	6.8
1	7,744 (26.9%)	8,263 (28.7%)	
2	5,758 (20%)	6,218 (21.6%)	
≥3	9,789 (34%)	9,213 (32%)	
Teaching status of the hospital			
Rural	1,612 (5.6%)	1,699 (5.9%)	1.5
Urban, non-teaching	9,040 (31.4%)	9,040 (31.4%)	
Urban, teaching	18,138 (63%)	18,052 (62.7%)	
Hospital region			
Northeast	5,326 (18.5%)	5,384 (18.7%)	1.1
Midwest	6,823 (23.7%)	6,737 (23.4%)	
South	12,265 (42.6%)	12,380 (43%)	
West	4,376 (15.2%)	4,290 (14.9%)	
Median household income for patient's ZIP code (Percentile)			
0-25th	9,299 (32.3%)	9,242 (32.1%)	1.9
26-50th	7,889 (27.4%)	8,090 (28.1%)	
51-75th	6,622 (23%)	6,622 (23%)	
76-100th	4,981 (17.3%)	4,837 (16.8%)	
Primary Payer			
Medicare/Medicaid	22,025 (76.5%)	21,593 (75%)	4.0
Private insurance	5,384 (18.7%)	5,844 (20.3%)	
Other/self-pay/no-pay	1,382 (4.8%)	1,353 (4.7%)	
Chronic limb ischemia	7,658 (26.6%)	7,831 (27.2%)	1.3

comparing "real-world" hospitalizations that underwent endovascular management versus surgical bypass in LE-PAD hospitalizations.

We observed higher hospitalizations with endovascular management in this study. The frequency of endovascular therapy is continuously increasing.[6,16,17] This number may be higher looking at recent changes in the reimbursement of endovascular management, which may have affected the number of endovascular management hospitalizations.[18] There are several reasons for the same: less invasive nature, patient's ineligibility for surgery, reduction in the threshold for the treatment due to advancement in the technology, higher durability, and changes in the provider's profile with more options. In accordance with 1 previously published

Table 3
In-hospital outcomes in propensity score-matched cohorts (1:1): stratified by intervention procedure and bypass surgery

Variables	Intervention procedure (N = 28,791)	Bypass surgery (N = 28,791)	p Value
In-hospital mortality	403 (1.4%)	720 (2.5%)	<0.001
Major amputation	288 (1%)	374 (1.3%)	0.001
Non-major amputation	1,238 (4.3%)	1,555 (5.4%)	<0.001
Gangrene	748 (2.6%)	950 (3.3%)	<0.001
Infection	2,476 (8.6%)	1,843 (6.4%)	<0.001
Acute renal failure	2,678 (9.3%)	3,397 (11.8%)	<0.001
Blood loss requiring transfusion	3,196 (11.1%)	5,930 (20.6%)	<0.001
Stroke	201 (0.7%)	230 (0.8%)	0.29
Disposition			
Home	18,829 (65.4%)	14,251 (49.5%)	<0.001
Transfer to other hospital/skilled nursing facility/intermediate care facility	9,415 (32.7%)	13,733 (47.7%)	
Against medical advice	144 (0.5%)	86 (0.3%)	
Length of stay, median (interquartile range)	3 (1-7)	5 (3-9)	<0.001
Cost ($), mean ± standard deviation	$25,577 ± $22,320	$26,397 ± $27,068	<0.001

study, endovascular therapy was offered to those with older age and higher co-morbidities.[19] The widely accepted recommendation is that a younger patient with longer life expectancy should undergo surgical bypass which is noticed in this study.[16,20] This is supported by only published randomized controlled BASIL trial which demonstrated better overall and amputation-free survival in the surgery group at 2 years.[8]

In-hospital mortality was observed to be lower with endovascular therapy in our study. Sachs et al demonstrated lower in-hospital mortality in their study which included hospitalizations with all indications and not specific to a single artery.[16] However, this study demonstrated higher amputation rates with endovascular therapy. This may be because the study included cohorts from 1997 to 2007. Our study includes more recent cohorts from 2012 to 2014 and with advancement in the field of endovascular therapy; we have noticed lower major as well as nonmajor amputation rates with endovascular therapy.[16] Ah Chong et al demonstrated lower wound complication rates with endovascular management as seen in our study.[21] These lower in-hospital outcomes may have translated to the shorter length of stay, higher chance of discharge to home, and lower cost of hospitalizations in this study after endovascular therapy which is also demonstrated in several other small studies.[19,22]

We have an important public health message from this study. Advancement in the field of endovascular management for LE-PAD has increased in the past decade. This includes but not limited to the endovascular management of complex LE-PAD with the use of atherectomy,[23] drug-eluting balloon catheters,[24] and microcatheters for the management of chronic total occlusion. Advancement in noninvasive imaging of LE-PAD before endovascular therapy helps localizing the lesions targeted for revascularization, the selection of appropriate equipment or adjunctive devices, and the choice of arterial access site which further maximizes procedural success.[6] LE-PAD involving long segments often crosses a joint line that makes it less ideal for the stents. Surgical revascularization was often preferred for such regions that may increase stent fracture because of greater compression, torsion, and stretch associated with flexion and extension of the joints. However, the development of drug-coated balloons with adjunctive atherectomy may address some issues associated with stent placement in these challenging arterial segments. A recently developed angiosome concept for the management of PAD may further improve outcomes. Older guideline using lesion length and type of lesion (stenotic vs occlusive) may not be valid to determine the mode of revascularizations for the management of LE-PAD. Careful patient selection along with this advancement for endovascular therapy can further improve short-term as well as long-term clinical outcomes. Based on these results, endovascular management might be the preferred approach for the management of LE-PAD. Results from the bypass versus angioplasty in severe ischemia of the leg-2 (BASIL-2)[25] and best endovascular versus best surgical therapy in patients with critical limb ischemia (BEST-CLI)[26] are awaited which will shed more light on the endovascular management of LE-PAD.

This study is associated with inherent limitations as with any retrospective and observational study. Additionally, this study does not include the severity of the disease such as Fontaine or Rutherford's classification or Trans-Atlantic Inter-Society Consensus. Even though we performed propensity score-matched analysis, several unmeasured confounders still remain which were not adjusted in this study. Anatomic site/lesion type could not be ascertained for our study cohorts. Aforementioned variables may have a significant effect on the clinical outcomes. Follow-up beyond discharge was not available to include in this study. We do not have information on salvage procedure performed in the groups. Finally, long-term follow-up have demonstrated comparable outcomes with endovascular treatment and open surgery in a decade back published BASIL trial.[8]

In summary, our study results demonstrate that endovascular management has improved short-term mortality and morbidity when compared with surgical bypass for the management of LE-PAD. Furthermore, endovascular therapy is associated with a shorter length of stay and less cost of hospitalizations as well. Taken together, these observations suggest that treatment decision for the management of LE-PAD should be carefully made as guidelines do not suggest preferential revascularizations method.

Disclosures

The authors have no conflicts of interest to disclose.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.amjcard.2018.08.018.

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