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Fewer Complications in the Obese Following Lower Extremity Endovascular Interventions

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Abstract

Background—The prevalence of obesity is increasing in the United States; however its impact on adverse outcomes in patients with peripheral vascular disease is not well studied. Obesity is associated with higher rates of complications following open bypass surgery, but limited data are available on its effect on endovascular intervention. This study aimed to identify whether obese patients suffer the same complications when undergoing lower extremity endovascular interventions.

Methods—All patients who underwent femoropopliteal or tibial endovascular interventions between 2011 and 2013 were identified in the Targeted Vascular Module of the NSQIP. Patients were stratified into five groups based on their body mass index (BMI): underweight (<18.6), normal weight (18.6–24.9), overweight (25–29.9), obese (30–34.9) and morbidly obese (≥35). Those patients without a documented BMI or a defined target lesion were excluded. Baseline demographics, patient characteristics, operative details, and outcomes were compared using univariate analysis between the BMI groups. Multivariable logistic regression was utilized to account for patient demographics and operative details.

Results—3,246 patients underwent endovascular interventions (78% femoropopliteal and 22% tibial). Of these, 137 (4%) were underweight, 881 (27%) were normal weight, 1,193 (37%) were overweight, 647 (20%) were obese and 388 (12%) were morbidly obese. There were no differences in 30-day mortality, however, surgical site infection (SSI) was higher in the morbidly obese (5% vs. normal weight: 2%, $P = .02$), whereas untreated patency loss was lower (morbidly

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obese: 0.5%, obese: 1%, normal weight: 2%, $P = .02$). Other important 30-day outcomes, including bleeding and amputation, were similar across the BMI groups. Following multivariate analysis, SSI remained more common in the morbidly obese (OR: 2.6, 95% CI: 1.4–5.0) while untreated patency loss remained lower in both overweight and morbidly obese patients (overweight: OR 0.5, 95% CI: 0.2–0.9, morbidly obese: OR: 0.2, 95% CI: 0.05–0.85). Length of stay >1 day was significantly lower in the overweight, obese and morbidly obese (OR 0.7, 95% CI: 0.6–0.8; OR 0.6, 95% CI: 0.5–0.7; OR 0.7, 95% CI: 0.5–0.9, respectively).

Conclusion—Few major complications occur in the obese in the first 30 days following endovascular interventions, and obesity is not an independent predictor of 30-day mortality. Rates of post-operative surgical site infections are low overall, though they are highest in morbidly obese patients (5%, compared to 2% in normal weight patients). Given this knowledge, endovascular interventions are a prudent treatment option for this patient population.

Introduction

Obesity is an increasing epidemic in the United States, affecting over 30% of the adult population.^{1, 2} However, the relationship between obesity and outcomes following vascular surgery is not fully understood. Prior work has suggested an “obesity paradox”, where a J-shaped mortality curve exists and obese patients with peripheral vascular disease (PVD) have an improved prognosis compared to underweight and normal weight patients.^{3, 4} This relationship was confirmed across a number of vascular surgery procedures and though the lowest mortality risk was seen in the overweight, the morbidly obese patients experienced the highest complication rates.⁵

Previously published data examining the relationship between body mass index (BMI) and open bypass using the National Surgical Quality Improvement Program (NSQIP) database found a higher occurrence of surgical site infection (SSI) in obese patients, and higher mortality rates in underweight and morbidly obese patients.⁶ These findings have also been confirmed in multiple single-institutional studies.^{7, 8} Obesity was shown to be an independent risk factor for increased length of stay following open revascularization.⁹

While these studies shed some light on the effects of obesity on lower extremity revascularization, they are specific to the open bypass patients, and do not reflect the rising utilization of endovascular treatment. Endovascular therapies utilizing angioplasty with or without combination stenting have provided a safe treatment option for many patients, including those not suitable for open procedures.¹⁰ Frequently, patients presenting for endovascular therapies have more comorbidities than those undergoing open bypass.^{11, 12} However, BMI as a comorbidity is not well described. A previous multicenter study showed lower mortality in the obese compared to underweight patients following lower extremity endovascular interventions; however, this did not assess other post-operative complications.¹³ Despite these data, obesity as an independent risk factor for post-endovascular complications has not been investigated on a national level.

Therefore, the goal of this study is to evaluate the relationship between BMI and postoperative complications following lower extremity endovascular interventions.

Methods

Database

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Targeted Vascular Module was utilized to identify all patients undergoing femoropopliteal or tibial endovascular interventions between 2011 and 2013. The targeted NSQIP is a national registry, developed in 2011, which contains data from over 65 self-selected hospitals interested in vascular-specific quality improvement. It collects patient demographics, operative details and 30-day outcomes from patients undergoing surgical procedures. Further information is available at www.facs.org/quality-programs/acs-nsqip.

Variables

Patient demographics, comorbid conditions, operative details and 30-day postoperative outcomes were identified for all patients. All variable definitions were specified by the NSQIP. BMI was calculated for each patient using height and weight information and the standard formula $BMI = \text{weight (kg)} / \text{height (m}^2\text{)}$.¹⁴ The patients were stratified into five groups based on their BMI, as defined by the World Health Organization (WHO): underweight (<18.6), normal weight (18.6–24.9), overweight (25–29.9), obese (30–34.9) and morbidly obese (≥ 35). Patients without a documented BMI or a defined target lesion were excluded. Smoking was defined as current tobacco use. Symptomatology was categorized as claudication or critical limb ischemia (rest pain or tissue loss). Procedure was classified as femoropopliteal if the primary procedure involved the common femoral, superficial femoral or popliteal arteries, or tibial if it was performed on the anterior tibial, tibioperoneal trunk, posterior tibial or peroneal arteries.

Postoperative outcomes were defined as those that occurred within 30-days. Surgical site infection or complication (SSI) was defined as non-healing or open wound, wound dehiscence or cellulitis at the surgical incision. Untreated loss of patency of treated arterial segment was defined as documented loss of patency (either by imaging, physical exam or surgeon diagnosis) and no subsequent procedure within 30 days of the index procedure. Amputation refers to major amputation (transtibial or proximal). Renal complications were defined as a post-operative creatinine rise greater than 2 mg/dL from baseline or new dialysis requirement. Pulmonary complications were defined as pneumonia, failure to wean from mechanical ventilation within 48 hours, re-intubation or pulmonary embolism. A composite variable of major adverse events constituted of: untreated patency loss, bleeding, myocardial infarction, stroke, SSI, re-intervention, amputation, 30-day mortality, renal complications and pulmonary complications. A detailed NSQIP variable guide is available at <https://www.facs.org/quality-programs/acs-nsqip/program-specifics/participant-use>.

Statistical Analysis

Statistical analysis was conducted using SPSS Statistics version 23 (IBM Inc., Chicago, IL). We compared BMI groups using univariate analysis. Chi-square analysis and Fisher Exact tests were utilized to compare categorical variables, and T-test, Mann-Whitney U test and Kruskal-Wallis test were used to assess continuous variables, as appropriate. Multivariable logistic regression was utilized to evaluate independent relationship between BMI and major

30-day outcomes. Normal weight was used as the reference group. Purposeful selection was used to distinguish inclusion variables for the model. This included all variables on the univariate analysis with $P < 0.1$, as well as those associated with complications from previous literature.¹⁵ We included: age, sex, race, body mass index, symptomatology, procedure location (femoropopliteal versus tibial), chronic obstructive pulmonary disease, congestive heart failure, hypertension, diabetes, dialysis, smoking history, pre-operative beta blocker use, history of bleeding disorder, operative time and functional status. Goodness of fit was confirmed for each model using Hosmer-Lemeshow test. A P-value of less than 0.05 was considered statistically significant.

Results

A total of 3,246 endovascular interventions were performed: 2,544 (78%) femoropopliteal and 702 (22%) tibial. Of these patients, 137 (4%) were underweight, 881 (27%) were normal weight, 1193 (37%) were overweight, 647 (20%) were obese and 388 (12%) were morbidly obese.

Demographics and Comorbidities

When patient baseline demographics were compared, the average age of patients decreased as BMI increased (Underweight: 72, Normal: 71, Overweight: 70, Obese: 70, Morbidly Obese: 64; $P < .001$). Additionally, the frequency of male sex (Underweight: 38%, Normal: 57%, Overweight: 64%, Obese: 62%, Morbidly Obese: 47%; $P < .001$) and white patients also differed (Underweight: 60%, Normal: 71%, Overweight: 75%, Obese: 76%, Morbidly Obese: 72%; $P = .001$) (Table 1).

Differences were additionally found within baseline comorbidities, as also summarized in Table 1. Overall, those patients with a higher BMI were seen to have an increase in comorbidities such as hypertension and diabetes, but patients with a lower BMI were more likely to smoke. This included: hypertension, diabetes, history of a bleeding disorder and smoking. No differences were seen in pre-operative dialysis, congestive heart failure or chronic obstructive pulmonary disease.

Operative Characteristics

When operative characteristics were compared, it was found that rates of claudication were highest in those with an elevated BMI (Underweight: 30%, Normal: 31%, Overweight: 41%, Obese: 46%, Morbidly Obese: 41%; $P < 0.001$). Conversely, treatment rates for CLI were higher in underweight and normal BMI patients: rest pain decreased as BMI increased (Underweight: 27%, Normal: 25%, Overweight: 20%, Obese: 17%, Morbidly Obese: 15%; $P < .001$) and tissue loss was “J-shaped” (Underweight: 43%, Normal: 44%, Overweight: 39%, Obese: 37%, Morbidly Obese: 45%; $P < .001$). No difference was seen in wound class, or location of intervention (femoropopliteal or tibial) Finally, no difference was found in operative time across the entire cohort, as well as within the femoropopliteal and tibial groups (Table 2).

Outcomes

There were no differences in 30-day mortality among different BMI categories (Underweight: 1%, Normal: 3%, Overweight: 1%, Obese: 2%, Morbidly Obese: 2%; $P = .3$). SSI rates increased as BMI did (Underweight: 2%, Normal: 2%, Overweight: 2%, Obese: 3%, Morbidly Obese: 5%; $P = .02$), whereas untreated patency loss decreased with increasing BMI (Underweight: 3%, Normal: 2%, Overweight: 1%, Obese: 1%, Morbidly Obese: 0.5%; $P = 0.02$). Length of stay (LOS) was significant across the BMI groups, with a U-shaped distribution. There was a significant difference in the median length of stay (LOS) across the BMI groups, with the lowest range of days in the overweight and obese patients. No difference was seen in bleeding, myocardial infarction/stroke, re-intervention, amputation or readmission. Additionally, pulmonary complications, renal complications and major adverse events were similar (Table 3).

Following multivariate analysis, morbid obesity was predictive of SSI (OR: 2.6, 95% CI: 1.4–5.0). Untreated patency loss was significantly lower in both overweight and morbidly obese patients (OR: 0.5, 95% CI: 0.2–0.9 and OR: 0.2, 95% CI: 0.05–0.9, respectively). Length of stay >1 day was significantly lower in the overweight, obese and morbidly obese (OR 0.7, 95% CI: 0.6–0.8; OR 0.6, 95% CI: 0.5–0.7; OR 0.7, 95% CI: 0.5–0.9, respectively). Amputation rates were initially significantly lower in the obese (OR: 0.5, 95% CI: 0.3–0.98), however, once claudicants were removed from the analysis, they were no longer significant (OR: 0.6, 95% CI: 0.3–1.2) (Table 4).

Discussion

This study found that BMI did not predict mortality and few major complications occur in the obese in the first 30 days following lower extremity endovascular revascularization procedures. A higher rate of surgical site infections was seen in both the obese and morbidly obese patient populations. Additionally, lower rates of untreated patency loss were seen in the overweight and morbidly obese.

Prior studies have shown increased surgical site infections in obese patients following open bypass operations. However, outcomes following endovascular procedures in this same patient population are less well studied. We found that surgical site infections following open bypass were seen in approximately 11% of all patients, and obesity was the strongest predictor with a 70% increased risk.⁶ Furthermore, obesity was associated with detrimental outcomes such as graft failure and post-operative sepsis, suggesting that patients at high risk for surgical site infections, such as obese patients, should be strongly considered for endovascular procedures. Additional work by Patel et al. revealed that though limb salvage rates were comparable between obese and non-obese patients, there was more than double the rate of wound infection in the obese (16% as compared to 7% in the non-obese).⁸

Surgical site infections following lower extremity revascularization represent a serious burden for patients. In addition to increased risk of early graft loss and rates of sepsis, they also result in increased lengths of stay, readmissions and higher hospital costs.^{16–20} In our study, we found that 60% of those with SSI's had a return to the operating room, which can pose a serious burden on a patient. Previous studies reported rates of SSIs following lower

extremity bypass to range from 5–11%, irrespective of BMI.^{6, 8, 21} Though there is a lack of literature on SSIs following endovascular interventions, in this study, we found that there were predictably lower rates, as compared to open bypass. The majority of the BMI groups had an infection rate of only 2%, and only the morbidly obese had rates as high as 5%. This is significantly lower than NSQIP average rates following open bypass. Furthermore, associated outcomes such as sepsis were not statistically significant, showing that the infections following endovascular procedures may be less severe than those following open bypass.

The benefit of the use of endovascular procedures over open procedures in the obese population is becoming an area of increased focus, with a shift towards the use of endovascular intervention over open surgical bypass in the past two decades.^{22, 23} Given the increased risk of SSIs in the obese, as well as the burden on patients, surgeons and hospitals due to this complication, current literature has recommended considering endovascular interventions in this patient population more frequently.^{6, 23, 24}

In our analysis, we found that obese patients have higher rates of surgical site infections. Given that our study was following endovascular intervention, not open bypass, we hypothesized this could be the result of a failure to utilize radiologic markers (such as ultrasound or fluoroscopy) while obtaining percutaneous vessel access, thus leading to increased bleeding and subsequent infection. Furthermore, due to the body habitus of these patients, hematomas may not be recognized as early as they normally would and subsequently lead to worse outcomes. Unfortunately, the variable for bleeding is defined as requiring transfusion or a secondary procedure, so it is possible bleeding played a role and we are unable to evaluate it. Alternatively, due to the more challenging anatomy present in obese patients, another explanation is that there could be an increase in the use of femoral cutdowns to gain access in this patient population. It is worthy to note that no difference was found in bleeding rates or operative times, reinforcing the safety of endovascular interventions in this population. We did evaluate the difference in SSI rates between claudicants and CLI patients, and found it was four times higher in the CLI population (1% vs 4%, respectively, $P < .001$). Though this was accounted for in our multivariable model, it is suggestive that CLI may be a predictor of wound infections.

In addition to the higher rate of SSIs, we also found there was a lower rate of untreated patency loss in the overweight and the morbidly obese. The explanation for this is likely attributable to the increased number of claudicants found in the obese population. While the overall proportion of patients undergoing intervention for CLI was consistently higher than for claudication across all the groups, the proportion of patients operated on for claudication increased stepwise as BMI increased. Those operated on for CLI have more diseased limbs than claudicants, and are an unhealthier population overall. Therefore, if a CLI patient lost patency post-procedurally, the surgeon may not have additional treatment options. Conversely, post-procedural patency may be less often evaluated in the obese, due to anatomical challenges or due to the higher rate of claudicants.

We additionally found a decreased rate of amputation within obese patients. We hypothesized this could also be reflective of the higher proportion of claudicants, and thus

less diseased limbs. To further evaluate this, we performed a subset analysis with only CLI patients, and found that amputation was no longer statistically significant, thus supporting our suspicions. Importantly though, this is reflective only of 30-day amputations, which are a rare event in claudicants. Long-term amputation outcomes could show a different result.

Lastly, an interesting relationship worth commenting on was that between age and obesity. We found that the morbidly obese patients had a mean age of six to eight years below the other populations. Though we cannot conclusively say why this group is receiving interventions at earlier age, we hypothesize they are experiencing more pain with walking, related not only to their peripheral vascular disease, but also their body habitus. Obesity increases a patient's risk of arthritis, causes increased demand on muscles to support a greater mass and predisposes patients to venous disease, such as varicosities.

There are several limitations to this study, most notably those related to utilization of a large multicenter database, such as NSQIP. Inherent to these registries are coding errors, missing data and limitations within the variables. For example, the targeted NSQIP database used for this study lacks variables for the site and direction of access (femoral ipsilateral antegrade versus femoral contralateral), the use of radiologic markers (such as ultrasound or fluoroscopy), percutaneous closure devices, as well as for the use of femoral cutdowns, leaving us unable to evaluate these as potential explanations for increased SSIs, though we hypothesize each were limited in use. Additionally, we are not able to determine the extent or depth of the SSIs seen, and the effects on the patients. Nor are we able to evaluate the use of groin versus remote arm access sites, which may impact SSI rates. Further information such resolution or improvement of disease and its relationship to untreated patency loss are also not available. Finally, the registry lacks follow-up beyond 30-days, thereby not allowing us to evaluate long-term patency, reinterventions or amputations.

Conclusion

There are few complications seen in the obese patient population following endovascular procedures. Similar to results found in open bypass patients, surgical site infections remain to be higher in the morbidly obese, though overall they occur much less frequently following endovascular interventions. This complication remains a serious concern for clinicians and can have detrimental effects on patients post-operatively. Additional work will need to be done to determine if there is a difference in the severity of the surgical site infections between endovascular and open bypass procedures, as well as the overall impact on the patient.

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Table 1

Patient Demographics

Baseline Characteristics		Underweight	Normal	Overweight	Obese	Morbid	P-Value
Number (%)	(N=137)	(N=881)	(N=1193)	(N=647)	(N=388)		
Age	71.6 $\pm$ 12.0	71.1 $\pm$ 12.4	69.5 $\pm$ 11.1	70 $\pm$ 10.7	63.5 $\pm$ 11		<0.001
Gender, Male	52 (38)	500 (57)	761 (64)	403 (62)	183 (47)		<0.001
Race, White	82 (60)	625 (71)	895 (75)	489 (76)	278 (72)		0.001
Comorbidities							
Dialysis	15 (11)	66 (8)	108 (9)	56 (9)	49 (13)		0.05
CHF	7 (5)	28 (3)	39 (3)	23 (4)	15 (4)		0.8
HTN	104 (76)	733 (83)	1041 (87)	566 (88)	352 (91)		<0.001
COPD	23 (17)	94 (11)	110 (9)	65 (10)	43 (11)		0.1
Diabetes	36 (26)	361 (41)	637 (53)	404 (62)	290 (75)		<0.001
Pre-op Medications							
ASA	100 (74)	725 (82)	989 (83)	572 (89)	329 (86)		<0.001
Statin	71 (53)	563 (64)	853 (72)	489 (76)	292 (76)		<0.001
Beta blocker	71 (53)	491 (56)	762 (64)	432 (67)	252 (66)		<0.001
Smoking (current)	61 (45)	324 (37)	333 (28)	185 (29)	101 (26)		<0.001
Bleeding Disorder	27 (20)	282 (32)	385 (32)	245 (38)	141 (36)		<0.001
Creatinine (>1.4)	22 (17)	185 (22)	277 (24)	149 (24)	105 (28)		0.05

Table 2

Operative Characteristics

Operative Characteristic	Underweight (N=137)	Normal (N=881)	Overweight (N=1193)	Obese (N=647)	Morbid (N=388)	P-Value
Op Time, median, Q1/Q3, min	91 (60, 136)	91 (62, 134)	87 (60, 128)	89 (65, 128)	86 (60, 125)	0.6
Symptomatology						
Claudication	41 (30)	277 (31)	490 (41)	296 (46)	158 (41)	<0.001
CLI: Rest Pain	37 (27)	219 (25)	241 (20)	112 (17)	57 (15)	
CLI: Tissue Loss	59 (43)	385 (44)	462 (39)	239 (37)	173 (45)	
Intervention Location						
Femoropopliteal	102 (75)	685 (78)	946 (79)	514 (79)	297 (77)	0.5
Tibial	35 (26)	196 (22)	247 (21)	133 (21)	91 (24)	

Table 3**Outcomes Following Endovascular Intervention Among BMI Groups**

Outcome	Underweight (N=137)	Normal (N=881)	Overweight (N=1193)	Obese (N=647)	Morbid (N=388)	P-Value
Number (%)						
LOS, median, Q1/Q3, min	1 (0, 6)	1 (0, 6)	1 (0, 4)	1 (0, 3)	1 (0, 6)	<0.001
30-day Mortality	1 (1)	22 (3)	16 (1)	10 (2)	7 (2)	0.3
Surgical site infection	2 (2)	20 (2)	28 (2)	22 (3)	20 (5)	0.02
Untreated Patency Loss	4 (3)	20 (2)	12 (1)	6 (1)	2 (1)	0.02
Amputation	4 (3)	40 (5)	48 (4)	15 (2)	11 (3)	0.2
Bleeding	9 (7)	74 (8)	78 (7)	41 (6)	33 (9)	0.4
Myocardial Infarction/Stroke	0	16 (2)	13 (1)	7 (1)	5 (1)	0.4
Reintervention	8 (6)	29 (3)	47 (4)	21 (3)	17 (4)	0.5
Pulmonary Complication	0	17 (2)	23 (2)	6 (1)	6 (2)	0.2
Renal Complication	2 (2)	9 (1)	7 (1)	4 (1)	6 (2)	0.4
Major Adverse Events	24 (18)	163 (19)	192 (16)	87 (13)	68 (18)	0.1
Readmission	23 (17)	114 (13)	175 (15)	78 (12)	59 (15)	0.3

Table 4**Multivariable Logistic Regression**

Outcome	Odds Ratio	95% CI	P- Value
30-day Mortality			
Underweight	0.2	0.03 – 1.8	0.2
Overweight	0.6	0.3 – 1.2	0.1
Obese	0.8	0.3 – 1.7	0.5
Morbidly Obese	1.0	0.4 – 2.4	0.96
Surgical Site Infection			
Underweight	0.6	0.1 – 2.7	0.5
Overweight	1.2	0.6 – 2.1	0.6
Obese	1.9	0.993 – 3.5	0.05
Morbidly Obese	2.6	1.4 – 5.0	0.003
Untreated Patency Loss			
Underweight	1.3	0.4 – 3.9	0.6
Overweight	0.5	0.2 – 0.9	0.03
Obese	0.4	0.2 – 1.03	0.06
Morbidly Obese	0.2	0.05 – 0.9	0.03
Length of Stay > 1 Day			
Underweight	0.95	0.6 – 1.4	0.8
Overweight	0.7	0.6 – 0.8	<0.001
Obese	0.6	0.5 – 0.7	<0.001
Morbidly Obese	0.7	0.5 – 0.9	0.008
Amputation			
Underweight	0.6	0.2 – 1.7	0.3
Overweight	1.0	0.6 – 1.5	0.8
Obese	0.5	0.3 – 0.98	0.04
Morbidly Obese	0.5	0.3 – 1.06	0.07
Amputation (CLI only)			
Underweight	0.5	0.2 – 1.7	0.3
Overweight	0.8	0.6 – 1.4	0.6
Obese	0.6	0.3 – 1.2	0.2
Morbidly Obese	0.7	0.3 – 1.4	0.3