Center-Level Variations in Maximum Recipient Body Mass Index in Heart Transplantation

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This study explored center-level variations in maximum recipient body mass index (BMI) and the associated impact of morbid obesity on outcomes of orthotopic heart transplantation (OHT). Using the United Network for Organ Sharing (UNOS) database, we examined adults (≥18 years) who underwent OHT between 2010 and 2018. Centers performing <10 OHTs per year were excluded. Recipients were stratified by BMI: <35, 35-38, 38 to 40, >40 kg/m2. Kaplan-Meier analysis was utilized to model survival and Cox regression analysis was utilized for adjusted analysis of 1-year mortality. A total of 17,821 candidates underwent OHT with 1,330 having a BMI >35kg/m2. Among 84 centers, a mean of 92.06% of recipients per center had a BMI<35 with 5.87%, 1.01%, and 1.06% of recipients having BMIs of 35 to 38, 38 to 40, and >40 at each center, respectively. A total of 5, 54, 17, and 8 centers had maximum recipient BMIs of <35, 35 to 38, 38 to 40, and >40 kg/m2, respectively. Centers performing OHT on recipients with higher BMIs displayed higher overall OHT volume (p = 0.002). Rates of post-transplant dialysis (p <0.001) and stroke (p = 0.008) were higher with increased BMI and length of stay was significantly longer (p <0.001). Following risk-adjustment, BMI 35 to 38 (HR 1.19) was not associated with increased risk of 1-year mortality although BMI 38 to 40 (HR 1.80, p = 0.007) and >40 (HR 2.85, p <0.001) were associated. In conclusion, most centers in the United States have a maximum recipient BMI of 35 to 38 for OHT, which appears justified as the risk of 1-year mortality increases with BMI >38. **(Am J Cardiol 2021;145:91–96)**

The prevalence of obesity continues to increase at an alarming rate across the country leading to new challenges and public health concerns.[1–2] Obesity has long been recognized as a major surgical risk factor associated with longer operating times, increased incidence of wound infections, and increased mortality.[3] For most solid organ transplantation patients, obesity and severe obesity continue to be listed as relative contraindications to surgery.[4-6] In orthotopic heart transplantation (OHT), the increasing burden of obesity further adds to the complexity of proper patient selection. With a stagnant donor supply and increasing incidence of refractory heart failure, patient selection has become more essential to preserve optimal outcomes. In OHT, morbid obesity (body mass index [BMI] > 35) has traditionally been considered a relative contraindication to transplantation.[7] Although obesity is correlated with adverse outcomes in heart transplantation, a maximum BMI cutoff continues to be debated. We aimed to explore center-level OHT practices and outcomes in recipients with severe obesity (BMI ≥35kg/m^2) who underwent OHT.

Methods

Utilizing the United Network for Organ Sharing and Scientific Registry of Transplant Recipients databases, we explored adult patients (≥18 years) who underwent OHT between January 1, 2010 and December 31, 2018. Patients who underwent multiorgan transplants (e.g. heart-lung, heart-kidney, etc.) or redo heart transplantation were excluded. Additionally, recipients who underwent OHT at centers that performed fewer than an average of 10 OHTs per year during the study period were excluded. Recipients were stratified by BMI into the following groups, which are typically considered as clinical ranges of maximum allowable BMI by most centers in the United States: <35, ≥35 to <38, ≥38 to <40, and ≥40kg/m^2. In an attempt to define more precise guidelines for transplantation in obese patients, we developed a rough estimate of maximum BMI transplanted at each center on the basis of their 5 highest BMI's transplanted during the study period.

Continuous data are reported as mean (standard deviation) for Gaussian data and median (interquartile range, IQR) for non-Gaussian data. Categorical data are reported as number (percentage). Chi-square testing was utilized for categorical data. One-way analysis of variance and Kruskal-Wallis testing were utilized for comparison of continuous data. Simple linear regression was utilized to compare maximum recipient BMI with total OHT volume at each center. Kaplan-Meier analysis was utilized to model one-year survival, stratified by BMI groups. Log-rank testing was used to compare survival curves. Cox regression

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Table 1
Recipient and donor characteristics for orthotopic heart transplantation, stratified by recipient body mass index (BMI)

	Body mass index (kg/m^2)					
Variable	Overall(n = 17,821)	<35(n = 16,491)	35-38(n = 983)	38-40(n = 178)	>=40(n = 169)	p-value
Recipient characteristics						
Age (years)	53.84 (12.40)	54.12 (12.39)	51.31 (11.61)	49.49 (11.88)	46.44 (13.10)	0.026
Female	4,722 (26.50%)	4,333 (26.27%)	281 (28.59%)	58 (32.58%)	50 (29.59%)	0.077
Male	13,099 (73.50%)	12,158(73.73%)	702 (71.41%)	120 (67.42%)	119 (70.41%)	
White	11,884 (66.69%)	11,089(67.24%)	600 (61.04%)	100 (56.18%)	95 (56.21%)	<0.001
Black	3,697 (20.75%)	3,289 (19.94%)	294 (29.91%)	55 (30.90%)	59 (34.91%)	
Hispanic	1,427 (8.01%)	1,334 (8.09%)	65 (6.61%)	17 (9.55%)	11 (6.51%)	
Other	813 (4.56%)	779 (4.72%)	24 (2.44%)	6 (3.37%)	4 (2.37%)	
BMI (kg/m^2)	27.48 (5.01)	26.71 (4.29)	36.25 (0.85)	38.84 (0.57)	42.78 (4.46)	<0.001
Diagnosis						<0.001
- Nonischemic cardiomyopathy	9,273 (52.03%)	8,478 (51.41%)	573 (58.29%)	108 (60.67%)	114 (67.46%)	
- Ischemic cardiomyopathy	6,273 (35.20%)	5,854 (35.50%)	326 (33.16%)	56 (31.46%)	37 (21.89%)	
- Congenital	490 (2.75%)	461 (2.80%)	18 (1.83%)	6 (3.37%)	5 (2.96%)	
- Restrictive	622 (3.49%)	599 (3.63%)	19 (1.93%)	2 (1.12%)	2 (1.18%)	
- Valvular	245 (1.37%)	239 (1.45%)	6 (0.61%)	0	0	
- Hypertrophic cardiomyopathy	480 (2.69%)	453 (2.75%)	19 (1.93%)	4 (2.25%)	4 (2.37%)	
- Other/unknown	438 (2.46%)	407 (2.47%)	22 (2.24%)	2 (1.12%)	7 (4.14%)	
Diabetes mellitus	4,756 (26.69%)	4,226 (25.63%)	406 (41.30%)	70 (39.33%)	54 (31.95%)	<0.001
Prior malignancy	1,529 (8.58%)	1,443 (8.75%)	64 (6.51%)	14 (7.87%)	8 (4.73%)	0.032
Steroid use	1,018 (5.71%)	950 (5.76%)	50 (5.09%)	8 (4.49%)	10 (5.92%)	0.908
Creatinine (mg/dL)	1.25 (0.61)	1.24 (0.61)	1.31 (0.53)	1.29 (0.45)	1.30 (0.62)	<0.001
Total bilirubin (mg/dL)	0.70 [0.50-1.10]	0.70 [0.50-1.10]	0.60 [0.401.00]	0.70 [0.50-1.00]	0.70 [0.50-1.10]	<0.001
Pulmonary capillary wedge pressure (mmHg)	17.71 (8.74)	17.74 (8.74)	17.20 (8.49)	17.49 (9.42)	17.95 (9.70)	0.067
Pulmonary artery systolic pressure (mmHg)	39.93 (13.85)	39.94 (13.87)	39.67 (13.37)	39.43 (13.04)	40.78 (15.29)	0.072
Left ventricular assist device	8,291 (46.52%)	7,433 (45.07%)	632 (64.29%)	121 (67.98%)	105 (62.13%)	<0.001
Intra-aortic balloon pump	1,246 (6.99%)	1,196 (7.25%)	37 (3.76%)	7 (3.93%)	6 (3.55%)	<0.001
Inotrope use	6,488 (36.41%)	6,158 (37.34%)	251 (25.53%)	44 (24.72%)	35 (20.71%)	<0.001
Functional status						<0.001
- Independent	2,457 (14.35%)	2,263 (14.28%)	139 (14.90%)	25 (14.62%)	30 (18.18%)	
- Partially independent	8,427 (49.23%)	7,704 (48.61%)	542 (58.09%)	96 (56.14%)	85 (51.52%)	
- Fully dependent	6,232 (36.41%)	5,880 (37.10%)	252 (27.01%)	50 (29.24%)	50 (30.30%)	
Donor characteristics						
Age (years)	32.17 (11.30)	32.13 (11.34)	32.81 (10.88)	31.48 (10.69)	33.09 (10.17)	0.053
Female	5,434 (30.49%)	5,101 (30.93%)	243 (24.72%)	43 (24.16%)	47 (27.81%)	<0.001
Male	12,387 (69.51%)	11,390 (69.07%)	740 (75.28%)	135 (75.84%)	122 (72.19%)	
White	11,484 (64.44%)	10,563 (64.05%)	673 (68.46%)	127 (71.35%)	121 (71.60%)	0.001
Black	2,930 (16.44%)	2,710 (16.43%)	161 (16.38%)	27 (15.17%)	32 (18.93%)	
Hispanic	2,907 (16.31%)	2,746 (16.65%)	127 (12.92%)	20 (11.24%)	14 (8.28%)	
Other	500 (2.81%)	472 (2.86%)	22 (2.24%)	4 (2.25%)	2 (1.18%)	
BMI (kg/m^2)	27.49 (6.02)	27.26 (5.90)	30.24 (6.39)	30.53 (7.07)	31.09 (7.35)	<0.001
Mechanism of death						0.058
- Trauma	8,587 (48.20%)	7,985 (48.43%)	451 (45.88%)	76 (42.70%)	75 (44.64%)	
- Cerebrovascular	3,745 (21.02%)	3,455 (20.96%)	214 (21.77%)	33 (18.54%)	43 (25.60%)	
- Drug overdose	2,239 (12.57%)	2,039 (12.37%)	142 (14.45%)	35 (19.66%)	23 (13.69%)	
- Other	3,245 (18.21%)	3,008 (18.24%)	176 (17.90%)	34 (19.10%)	27 (16.07%)	
Ejection fraction (%)	61.62 (6.68)	61.59 (6.68)	61.99 (6.55)	61.88 (7.18)	61.55 (6.77)	0.431
Inotrope use	7,525 (42.48%)	6,956 (42.24%)	416 (42.36%)	75 (42.13%)	78 (46.43%)	0.763
Transplant characteristics						
Ischemic Time (min)	188 [143-227]	188 [143-227]	188 [141-227]	183 [144-222]	191 [146-236]	0.641

analysis, utilizing all available recipient and donor characteristics, was employed to model unadjusted and adjusted 1-year survival. All hypothesis testing was two-sided. Statistical analyses were performed using the Stata 16 software package (StataCorp, 2017, *Stata Statistical Software: Release 16*, College Station, Texas). This study was approved by the Institutional Review Board at the University of Pittsburgh.

Results

A total of 17,821 patients underwent OHT during the study period (Table 1). Among the BMI groups, 16,491 (92.54%) patients had a BMI <35, 983 (5.52%) had a BMI ≥35 but <38, 178 (0.97%) patients had a BMI ≥38 but <40, and 169 (0.95%) had a BMI ≥40. Between the groups, there were significant differences in recipient age (p = 0.026), diagnosis (p <0.001), left ventricular assist device use (p <0.001),

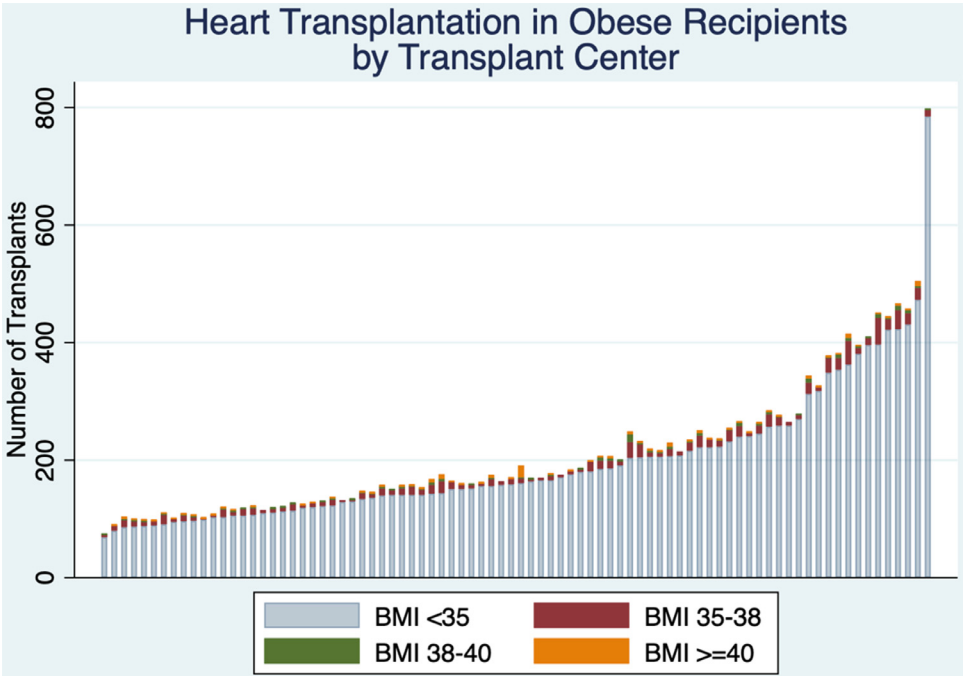

Figure 1. Heart transplantation volume by center displaying the number of recipients with a body mass index (BMI) <35, 35-38, 38 to 40, and ≥40.

and functional status (p <0.001). There were no significant differences in donor age (p = 0.053). Donor BMI was significantly higher in the highest recipient BMI group (p<0.001). Total ischemic time did not vary significantly between the recipient BMI groups (p = 0.641).

A total of 84 centers were included. Among the centers, the mean percentage of recipients with a BMI <35 was 92.06±4.06%. Mean percentages for recipients in the other groups included 5.87±2.79% for BMI 35 to 38, 1.01± 0.94% for BMI 38 to 40, and 1.06±1.46% for BMI ≥40. The distribution of recipient BMIs at each center is shown (Figure 1). When examining the maximum BMI of recipients who underwent OHT at each center, the mean was 42.62±5.96 kg/m^2. A sub-analysis stratifying each center by the 5 greatest recipient BMIs transplanted at each center revealed a significantly greater overall OHT volume in the centers utilizing higher BMIs (Table 2). Notably, increasing maximum BMI was associated with higher transplant volume per center. Stratification of these centers also revealed that 54 of the 84 centers had a maximum BMI between 35 to 38 with only 25 centers transplanting patients with a BMI >38. There was no significant association between maximum recipient BMI at each center and total center volume (R^2<0.001, p = 0.805).

One-year survival after-OHT was significantly different between the BMI groups (p <0.001) (Figure 2). Survival rates were 91.89%, 91.10%, 85.39%, and 80.44% in the 4 BMI groups, respectively. In an unadjusted analysis, recipient BMI 38 to 40 (HR 1.90, p = 0.003) and BMI ≥40 (HR 2.70, p <0.001) were significantly associated with 1-year mortality (Table 3). Utilizing Cox regression to adjust for recipient and donor characteristics, recipient BMI 38 to 40 (HR 1.80, p = 0.007) and ≥40 (HR 2.85, p <0.001) remained significantly associated with 1-year mortality, although BMI 35 to 38 did not (HR 1.19, p = 0.143). Additionally, older recipient age (HR 1.02, p <0.001), LVAD use (HR 1.31, p <0.001), and increased donor age (HR 1.01, p <0.001) were also associated with death. Both 30-day and 1-year survival were significantly different between the BMI groups (Table 4). Additionally, rates of post-OHT dialysis, stroke, and pacemaker placement varied significantly between the groups. Median length of stay was significantly longer in the higher BMI groups (median 15 days for BMI <35, 16 days for BMI 35 to 38, and 17 days for BMI 38 to 40 or ≥40). There were no significant differences in the rates of acute rejection requiring treatment (p = 0.075).

Table 2
Stratification of orthotopic heart transplantation (OHT) total volume based on the top 5 maximum recipient body mass index (BMI) values

	Maximum body mass index (kg/m^2)				
	>=30 (n = 5)	35-38 (n = 54)	38-40 (n = 17)	>=40 (n = 8)	p-value
Total OHT volume					
- Mean (SD)	142.6 (30.15)	189.9 (117.5)	268.4 (119.3)	285.4 (124.7)	0.016
- Median [IQR]	134 [117-173]	116 [119-234]	230 [168-389]	250 [175-397]	0.002

Abbreviations: IQR = interquartile range; OHT = orthotopic heart transplantation; SD = standard deviation.

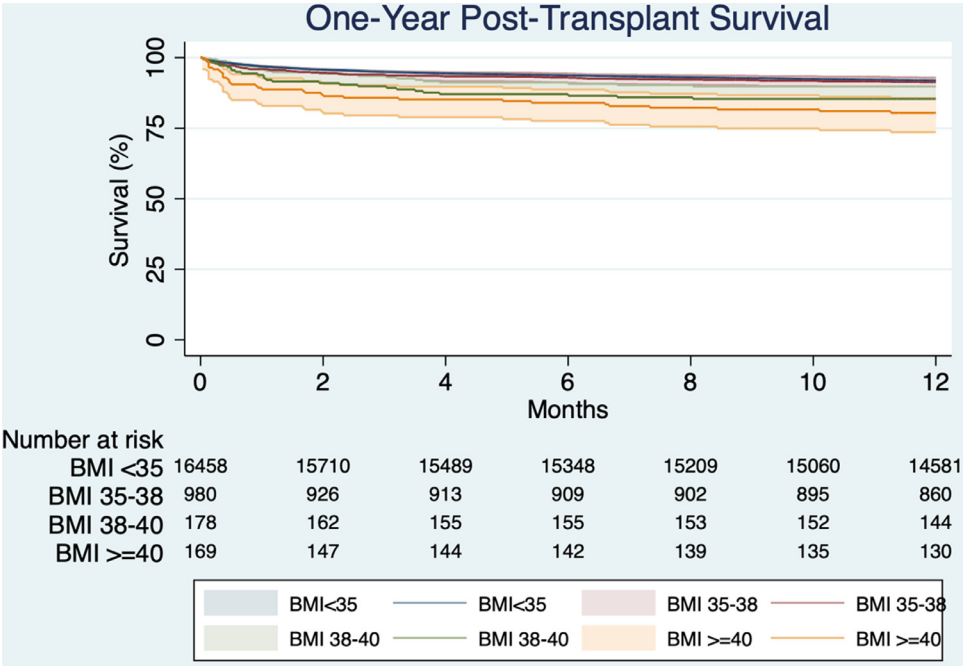

Figure 2. Kaplan-Meier analysis 1-year after-transplant survival stratified by recipient body mass index (BMI).

Discussion

The study examined the effects of BMI > 35 on outcomes and mortality in OHT. We demonstrated that recipients with BMI 38 to 40 and BMI > 40 had increased unadjusted and adjusted 1-year mortality, although patients with BMI 35 to 38 did not. The threshold of maximum allowable recipient BMI of 35 to 38, which we found most centers in the United States to practice, therefore appears justified. Patients with BMI > 38 were also found to have elevated risk for after-OHT dialysis, stroke, and pacemaker placement as well as longer length of stay.

The optimum cutoff for OHT in obese patients continues to be debated and examined due to conflicting evidence. Early studies demonstrated an increase in mortality in obese and cachectic patients despite similarities in rates of acute rejection, infection, and allograft arteriopathy.[8] In their retrospective study of 474 patients, Lietz et al. showed an increased mortality at 1 month (12.7% vs 7.6%) as well as significantly increased mortality at 5 years (53% vs 27%) in patients with a BMI > 30. Obese patients also experienced a shorter interval to high grade acute rejection and increased annual frequency of rejection.[9] Conversely, despite having higher rates of wound complications, patients with BMI > 30 in the study by Kocher et al. had similar survival compared with their counterparts.[10] Weiss et al. also failed to reveal a difference in mortality at 30 days, 90, days, and 1 year but did show a lower likelihood for obese patients to receive a transplant while on the waiting list.[11]

Subsequent studies continued to produce conflicting data with trends toward higher morbidity and mortality in obese patients. One such study by Russo et al. stratified 19,593 patients from the Cardiac Transplant Research Database into standard BMI classes including obese I (BMI 30-35) and obese II/III (BMI >35) and found that mortality was significantly increased in obese II/III patients at 1, 5, and 10 years with no significant differences in the obese I class.[12] Increasing BMI was also associated with new onset hypertension, hyperlipidemia, and diabetes after-transplant as well as increasing rates of rejection.[12] Rasco et al. showed an increased mortality at 1 year in patients with BMI >25 along with higher incidence of primary graft failure.[13] In a previous study examining metabolic risk factors in 15,960 patients, Kilic et al. weighed the effects of hypertension, diabetes mellitus, and obesity on mortality after OHT and discovered that obesity (BMI > 30) independently increased mortality and that the addition of each risk factor increased mortality exponentially.[14] Another report analyzing the relationship between age and obesity found higher mortality in overweight (BMI 25 to 30) and obese (BMI >30) patients aged 18 to 40 when compared with their elder counterparts.[15] Nagendran et al. argue that obese patients (BMI 30 to 35) should not be excluded from heart transplantation on the basis of similar outcomes and mortality. Morbidly obese patients (BMI >35), however, demonstrated significant differences in after-op outcomes and mortality, replicating previous findings.[16] In a study examining donor obesity on OHT outcomes, Shudo et al. found no difference in overall survival when comparing 4 separate donor BMI cohorts.[17] A more recent meta-analysis recommended adjustment of transplant criteria due to increased mortality in patients with a BMI >30.[18] Obesity in OHT was also associated with increased death from myocardial infarction, infection, chronic rejection, renal dysfunction, stroke, and diabetes utilizing data on 38,498 patients from the International Society for Heart and Lung Transplantation Registry.[19]

In our analysis, similar trends are observed with increased BMI associated with worse outcomes and increased mortality. The stratification of patients with BMI > 35 allows for

Table 3
Unadjusted and adjusted Cox regression analysis of one-year after-transplant mortality

Unadjusted			
Variable	Hazard ratio	95% confidence interval	p-value
Recipient BMI (kg/m^2)			
- <35	Reference	Reference	Reference
- 35-38	1.12	0.90-1.40	0.319
- 38-40	1.90	1.25-2.89	0.003
- >=40	2.70	1.84-3.96	<0.001

Adjusted			
Variable	Hazard ratio	95% confidence interval	p-value
Recipient BMI (kg/m^2)			
- <35	Reference	Reference	Reference
- 35-38	1.19	0.94-1.51	0.143
- 38-40	1.80	1.17-2.77	0.007
- >=40	2.85	1.96-4.16	<0.001
Recipient age	1.02	1.01-1.02	<0.001
Diagnosis			
- Nonischemic cardiomyopathy	Reference	Reference	Reference
- Ischemic cardiomyopathy	1.09	0.96-1.24	0.174
- Congenital	2.32	1.69-3.18	<0.001
- Restrictive	1.52	1.15-1.98	0.002
- Valvular	1.03	0.63-1.70	0.897
- Hypertrophic cardiomyopathy	1.07	0.73-1.56	0.738
- Other/unknown	0.95	0.62-1.44	0.798
Chronic steroids	0.64	0.48-0.86	0.003
Diabetes	1.14	1.01-1.98	0.002
Recipient inotrope use	0.84	0.73-0.97	0.019
Creatinine level	1.11	1.07-1.14	<0.001
Total bilirubin level	1.08	1.06-1.10	<0.001
Pulmonary artery systolic pressure	1.01	1.00-1.02	0.002
Pulmonary capillary wedge pressure	0.99	0.98-0.99	0.020
Left ventricular assist device	1.31	1.14-1.50	<0.001
Functional status			
- Independent	Reference	Reference	Reference
- Partially independent	1.21	1.01-1.45	0.038
- Fully dependent	1.60	1.31-1.94	<0.001
Donor age	1.01	1.01-1.02	<0.001
Donor gender male	0.82	0.73-0.92	0.001
Mechanism of death			
- Trauma	Reference	Reference	Reference
- Cerebrovascular	1.13	0.97-1.32	0.103
- Drug overdose	0.81	0.67-0.97	0.019
- Other	0.96	0.83-1.12	0.639

identification of a more precise cutoff reflecting a decline in outcomes and mortality. In this multicenter study, we found that only 5% of heart transplant patients had a BMI of 35 to 38 and 1% had a BMI of 38 to 40 or >40 each, respectively. These numbers are expected given the poor outcomes in this cohort as well as the relative contraindication to transplantation in patients with a BMI >35. Interestingly, our data demonstrated significant trends towards younger age and increased functional status in obese patients. This suggests that surgeons likely pursue transplantation in these patients due to their age and functional status despite their relative contraindication of obesity. These patients also had significantly higher rates of LVAD support suggesting that other durable support options were exhausted. Total donor ischemic time did not vary significantly between BMI groups reflecting previous literature.[13,16]

Based on our sub-analysis stratifying centers based on their 5 highest recipient BMI's, it appears reasonable to accept a BMI maximum of 38 with the caveat that individual center preferences may vary based on transplant volume. Regardless, consensus by center seems to indicate a relative disinclination to transplant patients with a BMI greater than 38. Our analysis of survival and after-operative morbidity in this cohort replicates previous findings but also challenges previous notions of OHT in morbidly obese patients. Patients with a BMI of 38 to 40 and >40 experienced significantly higher mortality compared with patients with a BMI <35 while patients with a BMI from 35-38 exhibited no significant difference in survival. Similarly, rates of after-OHT stroke, dialysis, and pacemaker placement increased significantly beyond a BMI of 38. These findings suggest that OHT in select morbidly obese patients.

The question arises with regards to how to manage end-stage heart failure in young patients who otherwise have no contraindications to transplant but have a BMI >38. Weight loss can be difficult for these patients, especially if they are euvolemic and additional diuretics will be of marginal benefit in terms of reducing overall body weight. Our data suggests that a BMI cut-off of 38 should be used and OHT deferred if possible in those patients with a higher BMI. Nonetheless, these decisions are made on an individual patient and individual center basis. More aggressive centers including those with higher annual OHT volumes may push the envelope in BMI cut-off in otherwise young patients with minimal comorbidity burden as they may argue that 80% 1-year survival after OHT is still better than the much higher anticipated mortality should OHT not be offered.

Table 4
After-transplant outcomes stratified by recipient body mass index (BMI)

	Body mass index (kg/m^2)					
	Overall(n = 17,821)	<35(n = 16,491)	35-38(n = 983)	38-40(n = 178)	>=40(n = 169)	p-value
30-day mortality	610 (3.42%)	538 (3.26%)	43 (4.37%)	11 (61.8%)	18 (10.65%)	<0.001
1-year mortality	1,510 (8.47%)	1,361 (8.25%)	90 (9.16%)	26 (14.61%)	33 (19.53%)	<0.001
Dialysis	1,914 (10.74%)	1,728 (10.48%)	120 (12.21%)	36 (20.22%)	30 (17.75%)	<0.001
Stroke	458 (2.78%)	458 (2.78%)	23 (2.34%)	5 (2.81%)	6 (3.55%)	0.008
Pacemaker placement	528 (2.96%)	492 (2.98%)	22 (2.24%)	10 (5.62%)	4 (2.37%)	0.008
Median length of stay	15 [11-22]	15 [10-22]	16 [11-24]	17 [12-28]	17 [12-26]	<0.001
Acute rejection	3,095 (19.59%)	2,837 (19.36%)	195 (22.60%)	34 (22.67%)	29 (22.14%)	0.075

Limitations of this study include those intrinsic to retrospective analyses. As this study relies on the United Network for Organ Sharing and Scientific Registry of Transplant Recipients databases, errors in data entry or significant omissions may have also affected our results. Selection bias among surgeons and transplant programs cannot be accounted for in a retrospective study such as the current study.

In conclusion, this study demonstrates that the majority of centers in the United States have a BMI cutoff of 38 for OHT. This appears justified as the adjusted hazards for 1-year mortality after OHT significantly increase above that threshold.

Credit Author Form

Bryant Fisher: methodology, formal analysis, writing - original draft; Lauren Huckaby: methodology, formal analysis, writing - original draft; Ibrahim Sultan: conceptualization, writing - review & editing, resources; Gavin Hickey: conceptualization, writing - review & editing, resources; Arman Kilic: conceptualization, methodology, formal analysis, writing - review & editing, resources, data curation, supervision.

Disclosures

The authors have no conflicts of interest to disclose.

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