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ORIGINAL ARTICLE

Effect of Body Mass Index on the Survival Benefit of Liver Transplantation

Shawn J. Pelletier,[1] Douglas E. Schaubel,[2,3] Guanghui Wei,[2] Michael J. Englesbe,[1] Jeffrey D. Punch,[1] Robert A. Wolfe,[3,4] Friedrich K. Port,[3,4] and Robert M. Merion[1,3]
[1]*Division of Transplantation, Department of Surgery, University of Michigan, Ann Arbor, MI;* [2]*Department of Biostatistics, University of Michigan, Ann Arbor, MI;* [3]*Scientific Registry of Transplant Recipients, Ann Arbor, MI;* [4]*Arbor Research Collaborative for Health, Ann Arbor, MI*

Obese patients are at higher risk for morbidity and mortality after liver transplantation (LT) than nonobese recipients. However, there are no reports assessing the survival benefit of LT according to recipient body mass index (BMI). A retrospective cohort of liver transplant candidates who were initially wait-listed between September 2001 and December 2004 was identified in the Scientific Registry of Transplant Recipients database. Adjusted Cox regression models were fitted to assess the association between BMI and liver transplant survival benefit (posttransplantation vs. waiting list mortality). During the study period, 25,647 patients were placed on the waiting list. Of these, 4,488 (17%) underwent LT by December 31, 2004. At wait-listing and transplantation, similar proportions were morbidly obese (BMI $\geq$ 40; 3.8% vs. 3.4%, respectively) and underweight (BMI $<$ 20; 4.5% vs. 4.0%, respectively). Underweight patients experienced a significantly higher covariate-adjusted risk of death on the waiting list (hazard ratio [HR] = 1.61; $P < 0.0001$) compared to normal weight candidates (BMI 20 to $<$25), but underweight recipients had a similar risk of posttransplantation death (HR = 1.28; $P = 0.15$) compared to recipients of normal weight. In conclusion, compared to patients on the waiting list with a similar BMI, all subgroups of liver transplant recipients demonstrated a significant ($P < 0.0001$) survival benefit, including morbidly obese and underweight recipients. Our results suggest that high or low recipient BMI should not be a contraindication for LT. ***Liver Transpl 13:1678-1683, 2007.*** © **2007 AASLD.**

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The prevalence of obesity has been steadily increasing in the United States.[1,2] As a result, more patients presenting with end-stage liver disease (ESLD) are obese and approximately 1 out of 5 are morbidly obese.[3] Because the surgical care of morbidly obese patients is difficult and associated with increased morbidity and mortality,[4] some transplant programs may be reluctant to offer liver transplantation (LT) to morbidly obese candidates.

Prior studies of LT among morbidly obese recipients have demonstrated mixed results. In a study of registry data, Nair et al.[3] found a higher incidence of primary nonfunction and mortality in morbidly obese patients. These findings led to the recommendation by the American Association for the Study of Liver Diseases that morbid obesity should be considered a contraindication to LT.[5] However, single-center studies have demonstrated acceptable outcomes in obese liver recipients when compared to non-obese controls.[6-11]

While the report by Nair et al.[3] focused on comparison of posttransplant outcomes in obese and nonobese recipients, published studies have not examined the effect of body mass index (BMI) on the survival benefit of LT.[12] Survival benefit analyses are designed to com-

Abbreviations: LT, liver transplantation; BMI, body mass index; HR, hazard ratio; NASH, nonalcoholic steatohepatitis; PY, patient years; ESLD, end-stage liver disease.

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Address reprint requests to Shawn J. Pelletier, MD, Assistant Professor of Surgery, University of Michigan Health System, 2926 Taubman Center, 1500 E. Medical Center Dr., Ann Arbor, MI 48109-0331. Telephone: 734-936-8363; FAX: 734-763-3187; E-mail: spelleti@med.umich.edu

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pare, among patients with ESLD on the waiting list, the survival of those who receive liver transplants to that of similar wait-listed patients who do not. Using statistical methods similar to those recently used to estimate survival benefit according to Model for End-Stage Liver Disease score,[12] the present analysis uses Scientific Registry of Transplant Recipients data to investigate the survival benefit of LT for candidates on the waiting list according to their BMI.

PATIENTS AND METHODS

A retrospective study of data obtained from the Scientific Registry of Transplant Recipients, as submitted by the members of the Organ Procurement and Transplantation Network, was performed to investigate risk factors for death after LT in recipients with varying BMI levels. Mortality ascertainment was supplemented through the Social Security Death Master File.[13]

All adult (≥18 yr old) patients wait-listed for deceased donor LT in the United States between September 1, 2001 and December 31, 2004 were eligible for inclusion in the study. Follow-up began at the date of initial wait-listing and remained under study until death, loss to follow-up, or until the conclusion of the observation period (December 31, 2004). Patients who received an exception score or a living donor transplant were censored at the date of receipt.

Etiologies of ESLD for all candidates placed on the waiting list were evaluated and included acute hepatic necrosis, cholestatic and noncholestatic cirrhosis, and others. In addition, the incidence of nonalcoholic steatohepatitis (NASH) was specifically investigated. Data reported to the Organ Procurement and Transplantation Network identified less than 0.5% of all candidates or recipients within any BMI category as having NASH. Because of the small group size and possible inaccurate reporting, further evaluation or adjusting of Cox models using NASH was not performed.

Patients were classified into 6 groups based on BMI. These included underweight (BMI < 20 kg/m^2), nonobese (20 to <25 kg/m^2), overweight (25 to <30 kg/m^2), obese (30 to <35 kg/m^2), severely obese (35 to <40 kg/m^2), and morbidly obese (≥ 40 kg/m^2).[3,14]

Patients were classified with respect to their BMI at the time of wait-listing and, if they received a liver transplant, at the time of transplantation. For transplant recipients, if updated weight or height measurements at the date of transplantation were not available, those recorded at wait-listing were used. Patients with no height or weight data recorded were not considered for analysis.

Waiting list and posttransplant crude (unadjusted) mortality rates were calculated using the ratio of deaths to patient years (PY) of follow-up based on several BMI categories.

Candidates contributed follow-up to the waiting list death rate group while on the waiting list and to the posttransplant group from the date of transplantation onward. Using an intent-to-treat analysis, candidates were not censored from the waiting list if they were removed for reasons other than death or transplantation (e.g., too ill; recovered function). Correspondingly, transplant recipients were not censored if graft failure occurred.

TABLE 1. Characteristics of Adult Candidates Wait-Listed for Deceased Donor LT in the United States Between September 1, 2001 and December 31, 2004 (n = 25,647)

	n	%
Age (yr)		
18-39	2,521	9.8
40-49	7,234	28.2
50-59	10,681	41.6
≥60	5,211	20.3
Gender		
Male	16,420	64.0
Female	9,227	36.0
Diagnosis		
Acute hepatic necrosis	1,730	6.8
Cholestatic cirrhosis	2,051	8.0
Noncholestatic cirrhosis	17,264	67.3
Other	4,602	17.9

NOTE: Adult means ≥18 yr old.

Cox proportional hazards regression was used to compare mortality by BMI category, adjusted for age, gender, race, ascites status, diagnosis, and Model of End-Stage Liver Disease score. At the time of wait-listing, the presence of ascites was coded within the Organ Procurement and Transplantation Network data as yes, no, or unknown; at time of transplant, the presence of ascites was coded as no, slight, moderate, or not available. For statistical analysis, these data were converted to a binomial form so that ascites of any extent was considered as having ascites. Models were fitted for waiting list, posttransplantation, and a model that combined waiting list and transplant experience such that the BMI-specific contrast between posttransplant and waiting list mortality could be estimated. Mortality contrasts were estimated by the hazard ratio (HR), which, for a particular group, can be interpreted as the ratio of the covariate-adjusted death rate for that group, divided by that of the reference group (HR = 1) at equal time after initial wait-listing. In addition, Cox nonproportional hazards models were fitted, which allowed the HR to vary with time since transplantation. All analyses were performed using SAS (v8.2; Cary, NC).

RESULTS

Between September 1, 2001 and December 31, 2004, a total of 25,647 patients were wait-listed for deceased donor LT in the United States. Characteristics of the entire study population are presented in Table 1. Most patients ranged from 40 to 49 yr old (28.2%) or 50 to 59 yr old (41.6%). Almost two-thirds of the patients placed on the waiting list were male. The most common etiology of liver failure was noncholestatic cirrhosis, ac-

TABLE 2. Distribution of BMI, Incidence of Ascites, and MELD Scores at Initial Wait-Listing and at LT

	At wait-listing			At transplant		
BMI (kg/m^2)	n (%)	Ascites (%)	Mean MELD	n (%)	Ascites (%)	Mean MELD
<20	1,146 (4.5)	51.5	17.5	181 (4.0)	67.4	23.0
20 to <25	6,745 (26.3)	55.3	16.4	1,161 (25.9)	77.7	21.8
25 to <30	9,184 (35.8)	55.4	16.1	1,648 (36.7)	81.6	21.8
30 to <35	5,358 (20.9)	58.9	16.0	944 (21.0)	84.9	21.4
35 to <40	2,227 (8.7)	58.6	16.4	402 (8.9)	84.5	22.6
≥40	987 (3.8)	60.1	17.5	152 (3.4)	87.5	24.7

Abbreviation: MELD, Model for End-Stage Liver Disease.

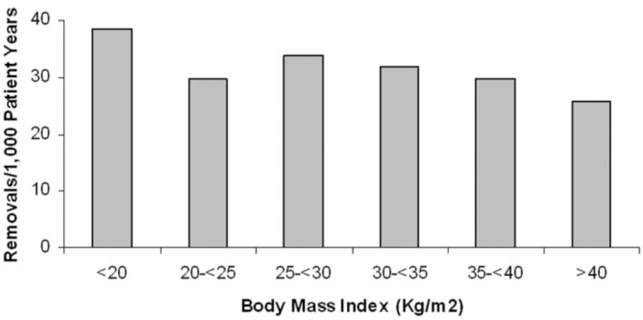

Figure 1. Crude (unadjusted) rate of removal from the waiting list by BMI category for reasons other than transplantation or death.

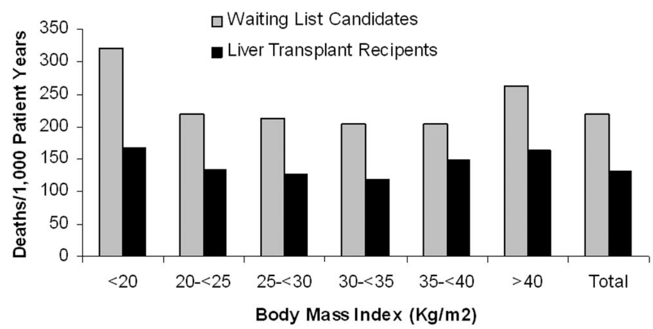

Figure 2. Crude (unadjusted) mortality rates by BMI category for waiting list candidates and liver transplant recipients.

counting for 67.3% of the cohort. The median time of follow-up posttransplantation was 1.39 yr (mean, 1.45 yr; maximum, 3.33 yr).

Comparison of the distribution of BMI between those who were wait-listed and those who received a liver transplant found no difference (Table 2). While the BMI of the majority of study subjects ranged between 20 and 35, approximately 9% of candidates and recipients were severely obese and 3% were morbidly obese. The distribution of Model for End-Stage Liver Disease scores were similar for all BMI categories at time of wait-listing and at time of transplant. The incidence of ascites appeared to increase with BMI at both time points.

As demonstrated in Figure 1, the unadjusted rate of removal from the waiting list for reasons other than transplant or death for patients with a BMI of 35 to 40 kg/m^2 (29.7/1,000 PY) was similar to that of patients with a normal BMI (29.7/1,000 PY); the rate of removal for patients with a BMI greater than 40 kg/m^2 (25.8/1,000 PY) was lower. Candidates with a BMI < 20 kg/m^2 (38.5/1,000 PY), 25 to <30 kg/m^2 (33.8/1,000 PY), and 30 to <35 kg/m^2 (31.8/1,000 PY) were noted to have higher rates of removal from the waiting list when compared to those with a normal BMI.

The overall unadjusted mortality rates for wait-listed candidates and for recipients were 218 and 132 deaths per 1,000 PY at risk, respectively. Figure 2 shows unadjusted waiting list and posttransplant mortality rates by BMI category. In both analyses, the crude mortality rates were highest at both extremes of BMI. In each BMI category, crude mortality rates were higher for candidates on the waiting list than for liver transplant recipients.

TABLE 3. Covariate-Adjusted Waiting List Mortality HRs by BMI Category for Liver Transplant Candidates

BMI (kg/m^2)	HR	95% CI	*P* value
<20	1.61	1.40–1.85	<0.0001
20 to <25	1.00	Reference	Reference
25 to <30	0.94	0.87–1.02	0.16
30 to <35	0.95	0.87–1.04	0.24
35 to <40	0.89	0.79–1.01	0.05
≥40	1.01	0.87–1.17	0.93

Abbreviation: CI, confidence interval.

Covariate-adjusted mortality HRs for liver transplant candidates on the waiting list are presented in Table 3. Compared to candidates on the waiting list with a normal BMI (20-24 kg/m^2), underweight wait-listed patients had a 61% increased risk of death (HR = 1.61, $P < 0.0001$). However, there was no difference in mortality for overweight (BMI 25 to <30 kg/m^2, HR = 0.94; $P = 0.16$), obese (BMI 30 to <35 kg/m^2, HR = 0.95; $P = 0.24$), severely obese (BMI 35 to <40 kg/m^2, HR = 0.89; $P = 0.05$), or morbidly obese candidates (BMI ≥ 40 kg/m^2, HR=1.01; $P = 0.93$) when compared to candidates with a normal BMI.

Similar findings were observed with respect to posttransplant mortality risk, except that the relative mortality risk for underweight recipients was not statisti-

TABLE 4. Covariate-Adjusted Posttransplant Mortality HRs by BMI Category for Liver Transplant Recipients

BMI (kg/m^2)	HR	95% CI	*P* value
<20	1.28	0.91–1.78	0.15
20 to <25	1.00	Reference	Reference
25 to <30	0.92	0.77–1.10	0.35
30 to <35	0.84	0.68–1.03	0.10
35 to <40	1.04	0.80–1.34	0.78
≥40	1.16	0.80–1.68	0.43

Abbreviation: CI, confidence interval.

cally different (HR = 1.28; P = 0.15) (Table 4). Recipients in higher BMI categories also did not demonstrate a significantly higher mortality risk than normal BMI range recipients.

In order to determine whether specific posttransplant periods were associated with especially high mortality risk, posttransplant hazard ratios were evaluated at selected intervals after transplantation (Table 5). For underweight patients (BMI < 20 kg/m^2), there was a 2-fold higher mortality risk in the first 7 posttransplantation days (HR = 2.05; P = 0.05) when compared to recipients with a normal BMI. This higher risk persisted through the remainder of the first month posttransplantation, but was not statistically significant. After the first month, the risk of mortality was similar for recipients with low and normal BMI. No differences in mortality were observed among overweight, obese, or morbidly obese recipients compared to those with normal BMI at any interval during the first posttransplant month or thereafter.

The survival benefit of LT by BMI category is shown in Table 6. In each BMI group, there was a significantly lower risk of death for liver transplant recipients compared to wait-listed candidates in the same BMI category. The lower risk of mortality for underweight recipients was present after the first week following LT (Table 7).

DISCUSSION

Obesity is now prevalent in more than 20% of patients undergoing LT.[7] While some single-center studies of obese liver transplant recipients have not demonstrated a difference in duration of surgery, cardiovascular complications, intraoperative transfusion requirements, or survival,[6,8-10] others have reported a higher rate of complications[7,11] and early mortality from multisystem organ failure.[11] An analysis of registry data by Nair et al.[3] that demonstrated higher incidences of primary nonfunction and mortality for obese liver transplant recipients led to a recommendation by the American Association for the Study of Liver Diseases in 2005 that morbid obesity should be considered a contraindication to LT.[5]

The initial intention of our analysis was to determine if a benefit exists for LT in obese recipients. While studies have demonstrated higher early[11] and overall mortality[3] for obese liver transplant recipients when compared to their nonobese counterparts, those studies did not consider the mortality of obese patients with ESLD who were denied access to LT. The present study, while limited in its ability to address the issue of denial of access to the waiting list because of high BMI, compared the mortality of candidates on the waiting list to that of liver transplant recipients to investigate the possible benefit or detriment of transplantation within BMI categories. Our finding of a similar risk of death for liver recipients with a BMI ≥ 40 kg/m^2 when compared to recipients with a normal BMI did not corroborate the findings of increased mortality reported by Nair et al.[3] Instead, our study found that obese patients, when compared to patients with normal BMI (20 to <25 kg/m^2), have a similar risk of death while on the liver transplant waiting list, have a similar survival rate following LT, and have a similar reduction in the risk of death. Although this study did not analyze quality of life following transplant, or length and cost of hospital stay, the significant survival benefit of LT demonstrated in obese liver recipients indicates that the American Association for the Study of Liver Diseases recommendation mentioned above should be reconsidered.

There are a few important differences between our study and the analysis by Nair et al.[3] The most important difference is the finding of a survival benefit for all categories of BMI. While Nair et al.[3] demonstrated an increased risk of death for obese liver transplant recipients, the risk of dying without transplantation was not considered in their publication. Our study demonstrates a clear survival benefit for liver transplant recipients when compared to their counterparts on the waiting list, regardless of BMI. In addition, Nair et al.[3] grouped all recipients with a BMI < 25 kg/m^2 as a single group, while the present study evaluated these patients as either having a normal BMI (20 to <25 kg/m^2) or being underweight (BMI < 20 kg/m^2). In our analysis, the group with the highest posttransplant mortality (underweight recipients) was removed from the control group. This should have, if anything, augmented the difference in mortality detected by Nair et al.[3] between morbidly obese recipients when compared to those with a normal BMI. While Nair et al.[3] identified higher mortality for morbidly obese liver recipients as early as 30 days posttransplantation and persisting at 5 yr, we identified no difference in mortality at any time period for morbidly obese vs. normal BMI recipients. Although this difference in findings is difficult to explain, a number of possible factors exist. Our analysis mainly included patients listed or receiving transplants within or just before the Model for End-Stage Liver Disease era, while the report by Nair et al.[3] evaluated patients receiving transplants between 1988 and 1996. Various improvements, including better patient selection, improved critical care support for transplant recipients, and other less well defined but nonetheless important increases in overall survival after LT during the 1990s[15] may at least partially explain why a difference in mortality was not identified in the present study for morbidly obese liver transplant recipients, but was

TABLE 5. Covariate-Adjusted Posttransplantation Mortality HR by BMI Category and Time Post-LT

	0-7 days posttransplantation			8-30 days posttransplantation			≥31 days posttransplantation		
BMI (kg/m^2)	HR	95% CI	*P*	HR	95% CI	*P*	HR	95% CI	*P*
<20	2.05	0.98–4.26	0.05	2.09	0.93–4.66	0.07	1.01	0.66–1.54	0.97
20 to <25		Reference			Reference			Reference	
25 to <30	1.15	0.71–1.89	0.57	1.09	0.66–1.80	0.75	0.86	0.70–1.05	0.14
30 to <35	0.93	0.51–1.69	0.82	0.92	0.50–1.68	0.77	0.81	0.64–1.03	0.08
35 to <40	1.35	0.68–2.71	0.39	1.26	0.60–2.64	0.55	0.96	0.72–1.29	0.79
≥40	1.77	0.72–4.36	0.21	1.87	0.80–4.37	0.15	0.95	0.60–1.51	0.82

Abbreviation: CI, confidence interval.

TABLE 6. Survival Benefit of Liver Transplantation by BMI Category

BMI (kg/m^2)	HR	95% CI	*P* value
<20	0.14	0.10–0.19	<0.0001
20 to <25	0.17	0.14–0.19	<0.0001
25 to <30	0.14	0.13–0.17	<0.0001
30 to <35	0.15	0.13–0.18	<0.0001
35 to <40	0.16	0.13–0.21	<0.0001
≥40	0.15	0.11–0.22	<0.0001

NOTE: The survival benefit is the covariate-adjusted relative risk of death for posttransplant liver transplant recipients compared to liver transplant candidates on the waiting list in the same BMI category.
Abbreviation: CI, confidence interval.

TABLE 7. Survival Benefit of Liver Transplantation by Time Posttransplant for Underweight Recipients

Time after liver transplantation	HR	95% CI	*P* value
0-7 days	1.07	0.56–2.03	0.84
8-30 days	0.48	0.25–0.91	0.02
≥31 days	0.08	0.05–0.12	<0.0001

NOTE: The survival benefit is the covariate-adjusted relative risk of death for liver transplant recipients compared to liver transplant candidates on the waiting list in the same BMI category. Underweight is BMI < 20 kg/m^2.
Abbreviation: CI, confidence interval.

present in the Nair et al.[3] cohort transplanted between 1988 and 1996. In addition, with increased experience, obese candidates at higher risk for mortality may now be more readily identified and carefully selected. However, the selection criteria pertinent to high-BMI patients cannot be identified from our analysis of national registry data. Our study does not propose that all morbidly obese patients with ESLD should be listed for LT. It does show, however, that among those placed on the waiting list and among those ultimately transplanted, current practice appears to result in successful selection.

Based on our analysis of data from a national registry, a difference in etiologies of ESLD between obese and nonobese patients was not identified. A higher incidence of NASH would be expected in obese candidates and recipients. However, data reported to the registry identified less than 0.5% of all candidates or recipients within any BMI category as having NASH, and a meaningful analysis could not be performed. Future studies should consider the possibility that candidates with NASH are being systematically excluded from listing or that there may be a higher risk of graft failure in morbidly obese recipients with NASH due to recurrent disease.

Although a number of studies have evaluated the effect of obesity on outcomes following LT, less attention has been given to potentially malnourished or underweight patients. Surprisingly, the present study demonstrated worse outcomes in some areas for underweight liver transplant candidates and recipients when compared to those with a normal BMI. Specifically, underweight candidates were found to have a higher removal rate from the waiting list and a higher risk of waiting list mortality (HR = 1.61). Though this finding did not reach statistical significance, underweight liver transplant recipients also had a tendency toward an increased risk of mortality following transplantation (HR = 1.28, P =0.15). When compared to the mortality risk for recipients with a normal BMI, the mortality risk for underweight recipients was higher during the first week after transplant but was not found to be different after the first month. Despite the increased risk of mortality, underweight recipients had a considerable decrease in mortality when compared to underweight patients on the waiting list, giving a clear survival benefit to those undergoing transplantation.

While prior studies have not demonstrated an increased mortality in underweight liver transplant candidates or recipients, other underweight or malnourished patient populations have been demonstrated to be at risk. Prior reports have demonstrated that low preoperative serum albumin levels are associated with an increased risk of morbidity and mortality after many surgical procedures.[16] In addition, a low BMI has been demonstrated to be an independent risk factor of mortality for seriously ill patients[17] as well as those undergoing cardiac surgery.[18,19] Underweight patients have higher waiting-list and posttransplantation mortality compared to those with a normal BMI, but a survival benefit was still conferred with LT. While underweight patients represented less than 5% of those wait-listed or receiving a transplant, these data suggest that, as for all potential liver transplant recipients, careful patient selection should be used for this population.

Although the current study has provided evidence that patients at both ends of the BMI spectrum have a significant survival benefit from LT, some limitations are apparent. Assessing BMI in patients with ESLD may not reflect the true extent of obesity. Many cachectic patients with chronic liver failure also have extensive peripheral edema or ascites. In these patients, elevated BMI may principally reflect fluid overload rather than obesity. In addition, the study population only included those patients who were deemed to be suitable candidates to be wait-listed for transplantation. Some patients with ESLD and either a high or low BMI may have been denied access the waiting list and therefore would not have been included in the analysis. Thus, a bias may be present whereby some underweight or obese patients with other unmeasured adverse factors may have been screened out and never added to the waiting list. Such a bias would have the effect of reducing the measured differences in survival benefit among BMI categories.

SUMMARY

A considerable proportion of patients on the liver transplant waiting list and undergoing LT are obese. Unlike previous studies, this study did not identify an increase in mortality for obese patients undergoing LT, including morbidly obese patients. In contrast, underweight liver transplant recipients were identified to be at an increased risk of death. However, all categories of BMI demonstrated a significant survival benefit when compared to their counterparts on the waiting list. Therefore, BMI alone should not necessarily exclude patients with ESLD from access to LT.

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