Table 3: Univariate and multivariate analysis.

Factors	HR (95% CI)	*P*	HR (95% CI)	*P*
Age	1.02 (1.01–1.03)	0.005	1.02 (1.01–1.03)	0.002
Gender		0.03		0.11
Female	1.0	—	1.0	—
Male	0.80 (0.65–0.98)	0.03	1.20 (0.96–1.49)	0.11
Diabetes mellitus		0.29		
No*	1.0	—	N/A	N/A
Yes	1.11 (0.91–1.36)	0.29		
BMI	1.00 (0.98–1.02)	0.72	N/A	N/A
Number of tumors		0.78		
1	1.0	—		
2	0.95 (0.77–1.17)	0.63	N/A	N/A
3	0.91 (0.67–1.24)	0.55		
Total Tumor Diameter	1.08 (1.01–1.16)	0.02	1.09 (1.01–1.18)	0.03
Liver directed therapy		0.04		0.06
No	1.0	—	1.0	—
Yes	0.82 (0.67–0.99)	0.04	1.22 (0.99–1.50)	0.06
Hepatitis B virus		0.47		
Negative	1.0	—	N/A	N/A
Positive	0.93 (0.77–1.13)	0.47		
Hepatitis C virus		0.02		0.004
Negative	1.0	—	1.0	—
Positive	1.26 (1.03–1.54)	0.02	1.34 (1.10–1.64)	0.004
Transplant criteria		0.22		0.32
Milan	1.0	—	1.0	—
UCSF	1.34 (0.84–2.15)	0.22	1.31 (0.77–2.21)	0.32

* Yes: type I or II; or type unknown.
HR: hazard ratio; CI: confidence interval; BMI: body mass index.

the benefit of downstaging via LDT in order to meet criteria, or to control disease while awaiting transplantation [18, 19]. Our results are not able to separately address the outcomes of patients who are initially outside of UCSF criteria on pretransplant imaging and subsequently undergo downstaging procedures to allow OLT. Additionally, due to the limitations of the database, information concerning the time interval from diagnosis to transplant and drop-out from the waiting list could not be ascertained.

The results of our study need to be carefully considered in light of our small patient cohort. Similar to other reported series, the number of patients in our study transplanted within UCSF criteria was small. However, the number of patients in our series beyond Milan criteria but within UCSF criteria ($n = 59$) compares favorably with Yao's two initial reports first establishing the UCSF criteria. Yao's initial series based on explant staging identified 18 patients meeting criteria and his subsequent analysis based on pretransplant imaging was based on 38 patients meeting UCSF criteria [9, 17]. However, given that the UNOS database covers nationwide transplant center reporting, we believe our findings may hold more weight in comparison to single institution series. Moreover, this is the largest multiinstitutional series comparing these two selection criteria within the United States patient population in the reported literature and the first time that the UNOS database has provided a comparison of transplantation outcomes for HCC based on selection criteria.

Before adopting an expanded size based criteria into the current UNOS allocation scheme, several questions require consideration. First, the ability to adequately stage patients with HCC remains a challenge. With current imaging modalities, understaging can be expected in 20–30% of patients, while overstaging can be seen in up to 15% of patients [20]. Given survival in patients with HCC beyond UCSF criteria is clearly inferior to survival within either Milan or UCSF criteria, further refinement of pretransplant staging is necessary to ensure size criteria validation. Furthermore, while size-based criteria may be comparable and reproducible in pretreatment staging, they may not predict the biologic aggressiveness of the underlying HCC. Recent evaluation into expanded criteria both from the University of Pittsburgh and a European multicenter series suggests that pathologic characteristics, in particular