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Review

Pushing the Boundaries for Liver Transplantation in Hepatocellular Carcinoma

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Abstract

Liver transplantation (LT) is the only curative treatment for unresectable or decompensated cirrhotic patients with hepatocellular carcinoma (HCC). Currently, the transplantable window for HCC patients is defined by meeting the extended transplant criteria. Notably, 20-30% of patients who beyond all established transplant criteria have demonstrated survival more than 10 years post-transplant, indicating that current selection criteria may exclude individuals who could significantly benefit from LT. Therefore, there is no perfect criteria currently, as these patients are excluded from the possibility of transplantation. Limits should be pushed to make LT possible for these patients.

Patients meeting the Expanded Malatya Criteria had a 78.4% 5-year overall survival (OS), a 4.7% recurrence rate, and a 35% Milan Criteria expansion rate, suggesting that the Expanded Malatya Criteria provide a reasonable approach for expanding transplant candidacy.

In cases of LT for patients with macroscopic portal vein tumor thrombus (Macro-PVTT), limited data from the Malatya experience indicate encouraging outcomes using living donor liver transplantation (LDLT): Macro-PVTT patients categorized as Vp1-3 with low alpha-fetoprotein (AFP ≤200) and gamma-glutamyl transferase (GGT ≤104) levels demonstrated five-year OS and disease-free survival (DFS) rates of 100% and 68.6%, respectively.

Another challenging cohort includes BCLC stage D patients, typically offered only supportive care with an expected median survival of three months. However, selected patients aged 18 to 65, CHILD class C, without extrahepatic spread and beyond Expanded Malatya Criteria, achieved a three-year survival rate of 50% following salvage LDLT.

In conclusion, during the era of LDLT, it is recommended that all HCC patients be evaluated in a multidisciplinary tumor board, irrespective of transplant criteria.

Keywords: Advanced HCC, live donor, macrovascular, macroscopic portal vein tumor thrombus, salvage liver transplantation, best supportive care

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Hepatocellular carcinoma (HCC) remains a global health concern. It is estimated that there will be 1.41 million new cases and 1.26 million deaths in 2045.[1] The Milan criteria (MC),[2] defined almost 30 years ago as patient selection criteria for liver transplantation (LT), which is the curative treatment for HCC because it eliminates both the underlying liver disease and the tumor, are not sufficient today and even the creators of the Milan criteria have expanded the MC three times.[3-5] How far can the MC be extended, reasonably? According to the EASL Clinical Practice Guidelines on the management of HCC 2025, If the patient within or slightly beyond MC is not suitable for downstaging due to the poor liver function, transplant listing may be considered which means MC can be expanded slightly.[6] On the other hand, according to the 2024 ILTS-ILCA consensus

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recommendations for LT for HCC, transplantation can be performed without downstaging if outcome measures are preserved.[7] The minimum acceptable 5-year survival rate after LT should be greater than 50%[7] or 60%.[6] Since all transplant criteria achieve this target survival,[8] we can say that the current transplantation limits are expanded criteria.

These criteria use parameters to predict the tumor's biological behavior. Predictors of tumor recurrence can be grouped into four main categories:

- **Morphological:** tumor number, largest tumor diameter, total tumor volume, sum of tumor diameters and tumor number.
- **Biological:** AFP, PIVKA-II (DCP), GGT, LRT response, PET/CT uptake.
- **Inflammatory:** neutrophil-to-lymphocyte ratio (NLR).
- **Histopathological:** microvascular invasion, poor differentiation.

Pushing the Boundaries for Liver Transplantation in Hepatocellular Carcinoma

Extended Transplant Criteria (Current limits for LT for HCC)

A chronological summary of the transplant criteria and scoring systems described in the literature is given in the Table 1 and 2.[9-35]

Our center in Türkiye established two transplant criteria—Malatya and Expanded Malatya Criteria—and published outcomes based on them.[36]

The expanded Malatya criteria had a 78.4% 5-year overall survival (OS), a 4.7% recurrence rate, and a 35% Milan criteria expansion rate, which would reasonably broaden transplantation boundaries (Fig. 1). However, regardless of the criteria used, 20-30% of patients who beyond any

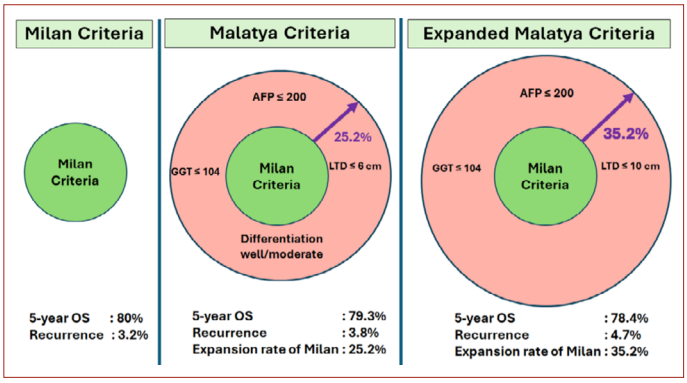

Figure 1. Summary of OS and DFS, recurrence rates, and Milan criteria expansion rates of patients within the criteria.

criteria have a 10-year survival with liver transplantation (Fig. 2). Therefore, there is no perfect criteria yet that would select patients who beyond these criteria but have a long survival rate. Therefore, all HCC patients should be discussed in a multidisciplinary tumor board, regardless of the criteria.

Liver Transplantation in Patients with Macroscopic Portal Vein Tumor Thrombus (Macro-PVTT)

Macroscopic portal vein invasion was previously a contraindication for liver transplantation, and all defined transplant criteria exclude these patients. Over time, studies have shown that patients with Macro-PVTT who respond well to downstaging and whose AFP levels are lower have acceptable liver transplantation outcomes.[37-41]

Therefore, it is no longer an absolute contraindication because liver transplantation outcomes are acceptable in selected patients with Macro-PVTT. Select patients with macrovascular invasion (Vp1 or Vp2) may be considered for LT if able to be successfully downstaged to local criteria (based on radiographic response, decrease in serum AFP). A minimum observation time of 12 months post-Downstaging may allow for assessment of tumor biology.[7]

In a study in which we retrospectively analyzed the liver transplantation results for patients with Macro-PVTT, after excluding those classified as Vp4 Macro-PVTT, the remaining 33 patients presenting with Vp1, Vp2, and Vp3 Macro-PVTT underwent liver transplantation. When we divided these 33 patients into two groups based on their final pre-transplant AFP and GGT blood levels (Group 1: low AFP + low GGT; Group 2: other combinations of AFP and GGT), the 5-year OS for patients with low AFP + low GGT (AFP ≤ 200 + GGT ≤ 104) (n=10) was 100% and the 5-year disease-free survival (DFS) was 68.6%.[43] (Fig. 3a and 3b). Although the sample size is small, the results are promising and LT boundaries can be extended even for patients with Macro-PVTT (AFP ≤200 + GGT ≤ 104).[42] Therefore, patients with PVTT should also be discussed in a multidisciplinary tumor board.

Pushing the limits by LDLT in HCC

Mazzafero et al.'s revised figure at the "Transplant Oncology Book" demonstrates the correlation between oncological acuity, organ allocation, and patient prioritization across various etiologies, it is noted that the transplantable window for cancer patients should be within the transplant criteria. Patients beyond the criteria are un-

Table 1. A summary of transplant criteria features as defined in the literature, presented in chronological order

Criteria	Single Tumor LTD, cm	Multiple Tumor (NN)	Multiple Tumor LTD, cm	TTD, cm	AFP, ng/mL	PIVKA -II	Differentiation	MiVi	LTD+ NN	TTV, cm^3	GGT, IU/L	5-year DFS, criteria in, %	5-year OS, criteria in, %	5-yr Recurrence, criteria in, %
Paul Brousse[9]	3	1-2	3	-	-	-	-	-	-	-	-	83	83	
Milan[2]	≤ 5	2-3	≤ 3	-	-	-	-	-	-	-	-	82 (4yr)	85 (4yr)	8
UCSF[10]	≤ 6.5	2-3	≤ 4.5	≤ 8	-	-	-	-	-	-	-		75.2	
BCLC[11]	≤ 7	2-3	≤ 5	-	-	-	-	-	-	-	-		80.2	23.8
		4-5	≤ 7											
Extended Criteria[12]	≤ 7.5	2-3	≤ 5	-	-	-	(>5 cm with poor diff also excluded)	-	-	-		76.8 (4yr)	82.9 (4yr)	
Berlin[13]	≤ 6	No limit	≤ 6	≤ 15	-	-	-	-	-	-	-	64 (3yr)	68 (3yr)	
Kyoto[14]	≤ 5	2-10	≤ 5	-	-	≤ 400	-	-	-	-	-		86.7	4.9
Tokyo[15]	≤ 5	2-5	≤ 5	-	-	-	-	-	-	-	-	94 (3yr)	75	
Onaca[16]	≤ 6	2-4	≤ 5	-	-	-	-	-	-	-	-	64.6		
Hangzhou[17]	≤ 8	-	-	≤ 8	-	-	-	-	-	-	-	70.7	62.4	
	>8	-	-	>8	≤ 400	-	Well/moderate				-			
Asan[18]	≤ 5	2-6	≤ 5	-	-	-	-	-	-	-	-		76.3	13.6 (3yr)
CUN[19]	≤ 6	2-3	≤ 5	-	-	-	-	-	-	-	-		73	
Valencia[20]	≤ 5	2-3	≤ 5	≤ 10	-	-	-	-	-	-	-		67	9
Shangai[21]	≤ 9	2-3	≤ 5	≤ 9	-	-	-	-	-	-	-	52.6	78.1	10.7
Kyushu[22]	≤ 5	No limit	≤ 5	-	-	≤ 300	-	-	-	-	-	87	82.7	
UpToSeven[4]	≤ 6	-	-	-	-	-	-	negative	≤ 7	-	-		71.2	39.9
TTV/AFP[23]	-	-	-	-	≤ 400	-	-	-	-	≤ 115	-		≈60 (4yr)	
Ext Toronto[24]	No limit	No limit	No limit	-	-	-	Well/moderate	-	-	-	-		68	25.6
AFP-TTD[25]	≤ 8	-	-	≤ 8	≤ 400	-	-	-	-	-	-	74.4		4.9
Samsung[26]	≤ 6	2-7	≤ 6	-	≤ 1000	-	-	-	-	-	-	89.6		
5-5-500[27]	≤ 5	2-5	≤ 5	-	≤ 500	-	-	-	-	-	-	73.2	75.8	7.3
Malatya[28]	≤ 6	No limit	≤ 6	-	≤ 200	-	Well/moderate	-	-	-	≤ 104		79.7	
Exp Malatya[29]	≤ 10	No limit	≤ 10	-	≤ 200	-	-	-	-	-	≤ 104		77.6	

AFP: alpha fetoprotein; GGT: Gamma glutamyl transferase; LTD: Largest tumor diameter; MiVi: Microvascular invasion; NN: Number of nodules; TTD: Total tumor diameter; TTV: Total tumor volume; PIVKA II: Protein induced vitamin K antagonist II.

Table 2. A summary of the scoring systems features as defined in the literature, presented in chronological order

Scoring System	Scores of the parameters					Posttransplant Recurrence Risk	5-year DFS in low risk	5-year OS in low risk	Recurrence in low risk, at 5-yr
AFP Model[30], 2012	LTD point	NN point	AFP point			Total point = score (0-9)		67.8	8.8
	≤ 3 cm = 0	1-3 nodule = 0	≤ 100 = 0			Score ≤ 2, low risk		47.5	50.6
	3-6cm = 1	>4 nodule = 2	100-1000 = 2			Score > 2, high risk			
	>6cm = 4		>1000 = 3						
RETREAT[31], 2017	LTD+NVT point	MiVi point	AFP at Tx point			Total point = score (0-8)			2.9
	0 = 0	Positive = 2	0-20 = 0			Score = 0,			75.2
	1.1-4.9 = 1		21-99 = 1			Score < 5, low risk			
	5.0-9.9 = 2		100-999 = 2			Score ≥ 5, high risk (RR)			
	≥10 = 3		≥1000 = 3						
MoRAL[32], 2017	Pre-Tx-MoRAL point		Post-Tx-MoRAL point			Total point = score (0-13)	97.4		
	LTD > 3cm = 3		LTD>3cm = 3			Score 0-2, low risk	75.1		
	NLR > 5 = 6		NN>3 nodules = 2			Score 3-6, medium risk	49.9		
	AFP > 200 = 4		Grade 4 tumor = 6			Score 7-10, high risk	22.1		
			MiVi positive = 2			Score > 10, very high risk			
NYCA[33], 2018	LTD at diagnosis Point	NN at diagnosis Point	AFP response Point			Total point = score (0-14)	90		cumulative
	0-3 cm = 0	1 nodule = 0	AFP always < 200 = 0			Score 0-2, low risk	70		7
	>3-6 cm = 2	2-3 = 2	Responders			Score 3-6, acceptable risk	42		27.5
	>6 cm = 4	≥4 = 4	Max > 200-1000 to final < 200 = 2			Score ≥7, high risk			62.5
			Max >1000 to final<1000 (must be 50% drop) = 2						
			Nonresponders						
			Max > 200-400 to final >200 = 3						
			Max > 400-1000 to final >200 = 4						
			Max > 1000 to final >1000 = 6						
Metroticket 2.05, 2018	LTD + NN ≤ 7 and AFP ≤ 200 or					Low risk	87.4	78	
	LTD + NN ≤ 5 and AFP 200-400 or								
	LTD + NN ≤ 4 and AFP 400-1000								
SNAPP[34], 2020	LTD point	NN point	AFP and PIVKA point	PET-CT point		Total point = score (0-8)	97		3
	≤ 3 cm = 0	1 nodule = 0	AFP≤150 + PIVKA≤100 = 0	Isometabolic = 0		Score ≤ 2, low risk	71		29
	3-6 cm = 1	2-3 nodule = 1	AFP≤150 + PIVKA>100 = 1	Hypermetabolic = 1		Score 3-4, medium risk	31		69
	>6 cm = 2	≥4 nodule = 2	AFP>150 + PIVKA≤100 = 2			Score > 5, high risk			
			AFP>150 + PIVKA>100 = 3						
R3-AFP Score[35],	LTD point	NN point	MiVi point	Nuclear Grade point	AFP point	Total point = score (0-11)		77.2	5.5
2022	≤ 3cm = 0	1-3 nodule = 0	Negative = 0	Well / Moderate = 0	≤ 100 = 0	Score 0, very low risk		67.8	15.1
	3-6cm = 1	>4 nodule = 1	Positive = 2	Poor = 1	100-1000 = 1	Score 1 - 2, low risk		57.2	39.1
	>6cm = 5				>1000 = 2	Score 3 - 6, high risk		19.8	73.6
						Score >6, very high risk			

AFP: alpha fetoprotein; LTD: Largest tumor diameter; MiVi: Microvascular invasion; MoRAL: Model Of Recurrence After Liver transplant; NLR: Neutrophile to lymphocyte ratio; NN: Number of nodules; NVT: Number of Viable Tumor, PIVKA II: Protein induced vitamin K antagonist II.

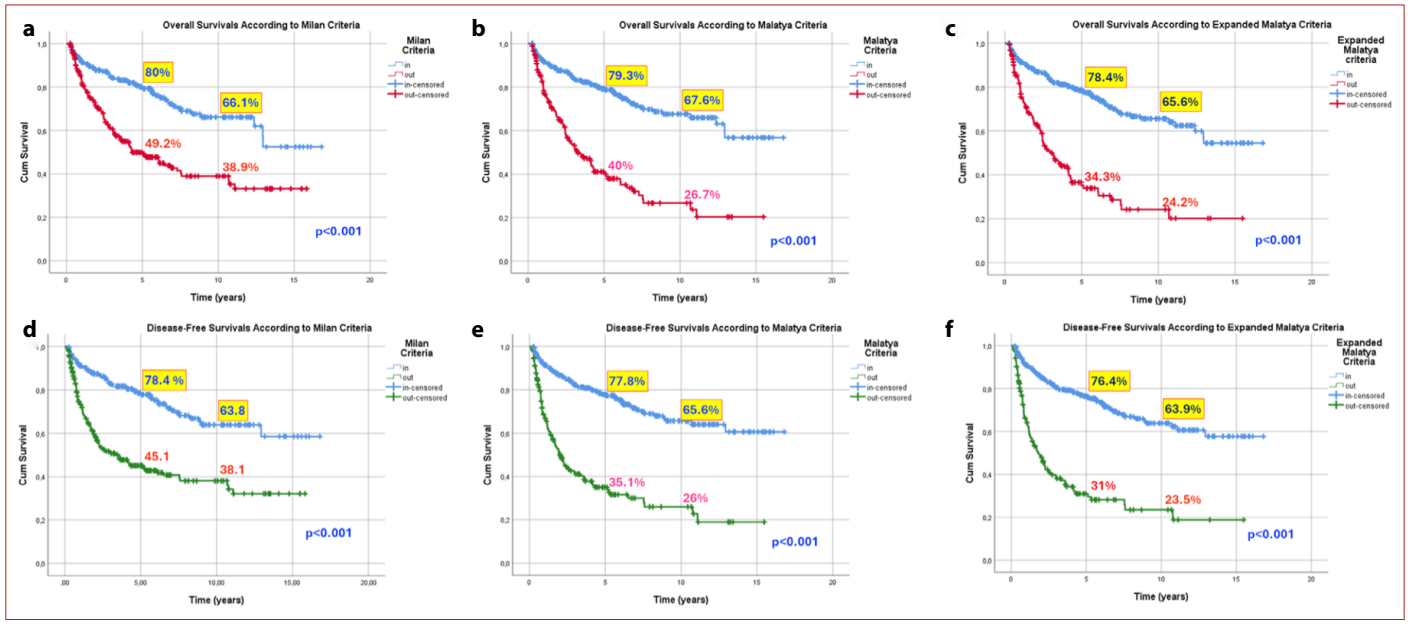

Figure 2. (a) Overall survivals according to Milan Criteria, **(b)** Overall survivals according to Malatya Criteria, **(c)** Overall survivals according to Expanded Malatya Criteria. **(d)** Disease-free survivals according to Milan Criteria, **(e)** Disease-free survivals according to Malatya Criteria, **(f)** Disease-free survivals according to Expanded Malatya Criteria.

likely to benefit from transplantation (Fig. 4a).[43] Setting these limits is justified when there is competition for deceased organs, as HCC patients beyond the criteria have only a 30% 10-year overall survival rate. Allocating the donated organ to the patient who is expected to benefit the most may be considered equitable; however, it is important to note that there are patients beyond the criteria who have a 30% 10-year overall survival rate by LT (Fig. 2). There is currently no perfect criteria that will select these patients beyond the criteria with longer survival by liver transplantation, and there will never be one. Because HCC is a highly heterogeneous tumor, and no single criteria can be applied to all HCC patients. "One size does not fit all" principle applies to HCC.

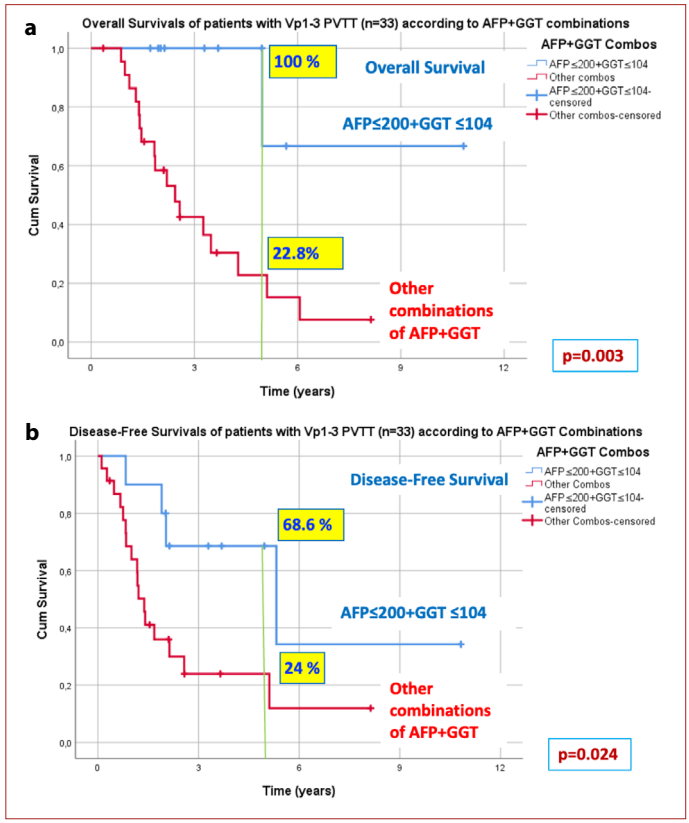

Figure 3. (a) Overall survivals of patients with Vp1-3 macro-PVTT according to AFP+GGT combinations. **(b)** Disease-free survivals of patients with Vp1-3 macro-PVTT according to AFP+GGT combinations.

However, living donor liver transplantation may allow us to push and even expand these limits. Because there is no competition for organs in LDLT, the rights of other patients on the cadaveric waiting list are protected, and it has the potential to provide an unlimited organ source. The expanded criteria above have been developed based on the outcomes of LDLT centers, and macroscopic PVTT is no longer an absolute contraindication. Therefore, this figure should be updated for LDLT. The transplantable window should also cover a subset of cancer patients beyond the criteria (Fig. 4b). It is important to note that patients who do not meet the established criteria have a 30% ten-year survival rate. The assessment of these patients' eligibility for liver transplantation should be conducted by multidisciplinary tumor boards, with careful consideration of individual patient and tumor characteristics.

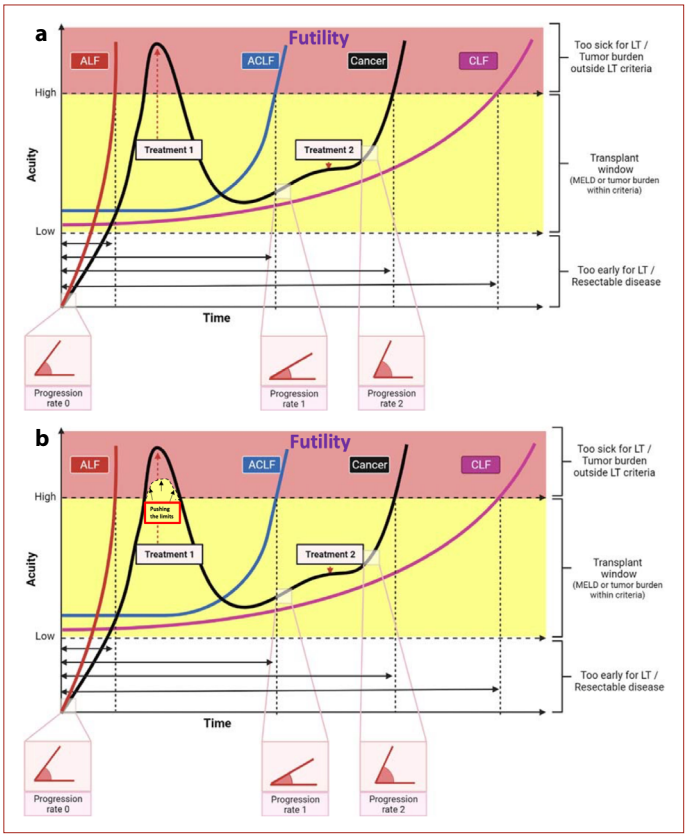

Figure 4. (a) The oncological acuity, organ allocation, and patient prioritization across various etiologies. Transplantable window is yellow area. **(b)** The oncological acuity, organ allocation, and patient prioritization across various etiologies. Updated Transplantable window is yellow area, in the LDLT era for cancer patients.

Salvage LDLT for Best Supportive Care Patients with Advanced HCC

Patients with advanced HCC and liver decompensation are classified as Stage D according to BCLC staging, and for these patients, only best supportive care is recommended because their impaired liver function does not allow downstaging procedures.

Patients with BCLC stage D have a median survival of three months. Young patients with decompensated cirrhosis and portal vein tumor thrombus often cannot receive LRT or systemic therapy due to poor liver function and typically receive only palliative care.

We conducted a retrospective study[44] to determine whether LDLT could benefit these patients by improving liver function (salvage LDLT=sLDLT). If tumor recurrence occurs after transplantation, preserved liver function enables further treatment—such as surgery, LRT, or systemic therapy—potentially leading to longer survival and improved quality of life.

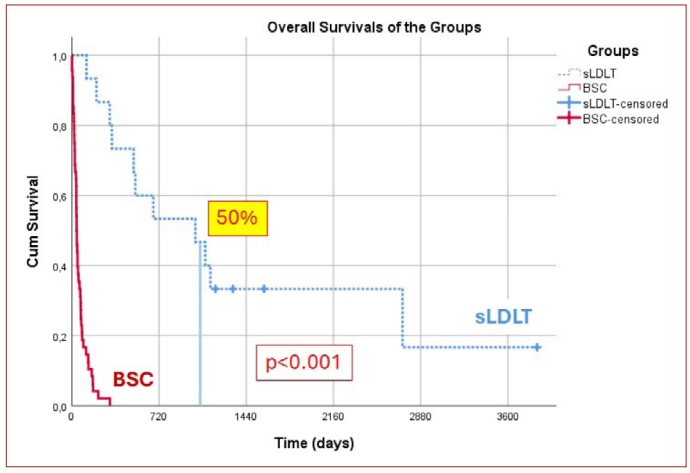

Figure 5. Overall survivals of the sLDLT vs BSC groups.

In this study, a 50% 3-year overall survival rate was observed following liver transplantation in patients aged 18 to 65 with CHILD class C, beyond expanded Malatya criteria, and without extrahepatic spread (Salvage LDLT Group n=17). For the BSC group (n=48), the median survival was 40 days. A 50% 3-year survival rate with LDLT, compared to a 40-day survival rate with BSC, is a remarkable result (Fig. 5).[44] Ongoing developments in systemic treatments may extend these survival rates.

In Conclusion, in the LDLT era, LT margins may need to be wider, but live donor hepatectomy complications should remain acceptable.

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