Digestive and Liver Disease 58 (2026) 1308–1313

Contents lists available at ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Liver, Pancreas and Biliary Tract

Liver transplant allocation by milan criteria may exclude eligible HCC patients without survival benefit – a post-hoc analysis of the SiLVER study

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ARTICLE INFO

Article history:
Received 24 February 2026
Accepted 22 July 2026
Available online 30 August 2026

Keywords:
Hepatocellular carcinoma
Liver transplantation
Milan
UCSF
Up-to-7
Metroticket 2.0
SiLVER study

ABSTRACT

Background and aims: Selection criteria for liver transplant allocation are crucial for benefit-risk assessment of every patient evaluated for liver transplantation (LTx). Currently, Milan criteria are the key decision tool in several countries to assess whether a patient with hepatocellular carcinoma (HCC) is eligible for LTx. In this post-hoc analysis of the SiLVER Study, we analysed the performance of Milan criteria compared to the broader criteria UCSF, Up-to-7 and MT 2.0 to assess whether there is need to reform the selection process of HCC patients evaluated for LTx.

Methods: Outcomes of 485 patients of the multicentre and randomized SiLVER Study were analysed determined by recurrence-free survival (RFS), overall survival (OS) and freedom of tumor (FoT).

Results: Discrimination was modest for all four criteria and showed no statistically significant differences across OS (C-index 0.55–0.57), RFS (0.57–0.59) or FoT (0.62–0.64), with Metroticket 2.0 numerically highest. In the competing-risks analysis, being outside any criterion was associated with an increased subdistribution hazard of recurrence (sHR 2.7–3.6, all $p < 0.001$). The broader criteria classified substantially more patients as eligible (Up-to-7 83.9% vs Milan 65.6%).

Conclusions: Our data based on explant histopathology suggest that Milan criteria exclude patients with HCC evaluated for LTx without demonstrable benefit, questioning Milan criteria as sole selection tool in many regions doing liver transplants.

1. Introduction

Hepatocelullar carcinoma (HCC) developed in a cirrhotic liver is a common indication for liver transplantation (LTx) [1]. However, especially given the current organ shortage, there is an ongoing discussion regarding the optimal cut-off for HCC patients eligible and not eligible for LTx.

In 1996, based on a cohort of 48 patients, Mazzaferro et al. [2] demonstrated LTx to be an effective treatment option for small unresectable HCC developed in cirrhotic livers and defined commonly used criteria that would achieve long-term survival for these patients. Those criteria, known as the Milan criteria, include the following parameters: one lesion not >5 cm, or up to three lesions smaller than 3 cm, with no extrahepatic manifestation and no evidence of gross vascular invasion. Since then, several studies have tried to expand those rather strict criteria. In 2003, Yao et al.[3] at the University of San Francisco (UCSF) expanded the criteria to include one lesion up to 6.5 cm or up to three lesions summing up to <8 cm, with the largest lesion not exceeding 4.5 cm. Following a large multicentre analysis, Mazzaferro et al.[4] in 2009 proposed the less restrictive Up-to-7 criteria, allowing tumor size and number to add up to a maximum of seven. Later in 2018, Mazzaferro et al.[5] updated a model called Metroticket (MT) 2.0 to determine risk of death from HCC-related factors after LTx, which (besides tumor number and size) also includes the tumor marker α-fetoprotein (AFP) level and therefore takes the individual's tumor biology into account. Here, an AFP titre <200 ng/ml allows the sum of tumor number and size to be seven, for <400 ng/ml to be

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https://doi.org/10.1016/j.dld.2026.07.082

five, and for <1000 ng/ml to be four. Derived from a large (341 patients), multicentre cohort, MT 2.0 predicted the HCC-specific survival five years after LTx to be 70%.

In our current post-hoc analysis of the SiLVER Study data[6], we analysed 485 patients that received LTx due to an HCC regarding the four selection criteria Milan, UCSF, Up-to-7 and MT 2.0. In this study we examined recurrence-free survival (RFS), overall survival (OS) and freedom of tumor (FoT) of the study cohort after categorization by each scoring system aiming to evaluate the rather strict Milan criteria versus the less restrictive alternative systems.

2. Methods

2.1. Study population

The SiLVER Study was a multicentre, randomized, open-labeled, parallel group trial (EudraCT: 2005–005,362-36; Clinicaltrials.gov: NCT00355862) that recruited 525 LTx recipients from 45 transplant centers across Europe (42), Canada (2), and Australia (1). Inclusion criteria were age ≥18 years, histologically proven HCC before randomization and signed written informed consent. Main exclusion criteria included extrahepatic HCC manifestations and non-HCC malignancies within the last 5 years. The SiLVER Study was conducted over a time period of approximately 8 years, starting with a 3-year enrolment period from January 2006 to April 2009 and a follow-up period of at least 5 years. The last patient visit was conducted in March 2014. 71.9% of patients received pre-transplant anti-tumour treatment.

2.2. Randomization

The study cohort was randomized into 2 groups. Group A consisted of patients receiving a center-specific mTOR inhibitor-free, generally calcineurin inhibitor-based protocol. Patients in group B received sirolimus mono- or combination therapy after 4 to 6 weeks of mTOR inhibitor-free immunosuppression.

In our analysis here, as shown in Supplementary Table 1, randomization of the study cohort regarding categorization into the respective HCC score was homogenous.

2.3. Outcomes

Primary endpoint of the SiLVER Study was RFS, with OS and FoT as secondary endpoints. RFS was defined as HCC recurrence or patient death. Each patient underwent a standardized follow-up at every scheduled visit. During the first year after LTx, patients were followed up after month 1, 3, 6, 9 and 12. Starting with the second year after LTx, patients were followed up every 6 months.

2.4. Post-hoc analysis

HCC criteria stratification was based on pre-surgery imaging and histopathological assessment of the explanted recipient liver. AFP titres were analysed pre-surgery.

2.5. Statistical analysis

Continuous variables are summarised as median (interquartile range) and categorical variables as counts (percentages). The four selection criteria (Milan, UCSF, Up-to-7, and Metroticket 2.0) were each evaluated as a binary classification (inside vs outside) against three endpoints: OS, RFS, and FoT. FoT was defined as freedom from HCC recurrence, with death without recurrence treated as a competing event. Patients were regarded as correctly classified if they were inside a score and survived 5 years.

Discrimination was quantified using Harrell's concordance index (C-index), estimated from a Cox proportional-hazards model for each criterion, for OS, RFS, and FoT. For the C-index, FoT was modelled as a standard time-to-recurrence outcome (death without recurrence censored). Pairwise differences in C-index between criteria were tested using the concordance variance estimator from the survival package, forming a contrast between paired C-indices.

Time-dependent discrimination and overall performance were assessed for all three endpoints at 1, 2, 3, 4, and 5 years using the time-dependent area under the ROC curve (AUC), the Brier score, and the index of prediction accuracy (IPA); each reported with 95% confidence intervals. For OS and RFS, predicted risks were obtained from Cox models; for FoT, from Fine-Gray models, with focus on recurrence. Inverse-probability-of-censoring weights for these metrics were estimated using the Kaplan-Meier method for the censoring distribution. Because each criterion yields only two predicted-risk values, Brier score and IPA are therefore reported as the calibration summary.

For FoT, death without recurrence was treated as a competing event. Recurrence was modelled using Fine-Gray subdistribution hazard regression, reporting subdistribution hazard ratios (sHR) with 95% confidence intervals for classification outside versus inside each criterion. Kaplan-Meier estimates for FoT are presented visually.

Pairwise between-criterion contrasts in time-dependent AUC and Brier score were computed without adjustment for multiplicity. Analyses were performed in GraphPad Prism V10.2.3 (Boston, USA) and R version 4.5.2 using the survival, riskRegression, prodlim, and tidycmprsk packages. A two-sided p-value < 0.05 was considered statistically significant. Tests were performed as indicated in the respective figure or table legends.

3. Results

3.1. Classification of study participants according to HCC scores

Each SiLVER Study patient was classified regarding Milan, UCSF, MT 2.0 and Up-to-7 criteria. Of the 525 initially included patients, 40 (7.6%) patients had to be excluded from the final analysis (Fig. 1). 17 patients were excluded due to violations of eligibility criteria, including 10 patients without histologically proven HCC, 5 patients with extrahepatic manifestations and 2 patients with non-HCC malignancy. 23 patients were excluded due to missing data regarding one or several scores; one patient had no information available about the number of tumors, 10 patients had missing AFP values, and data was not available for 12 patients regarding time spent on the waiting list for LTx.

Of the 485 patients included in this post-hoc analysis (Table 1), 318 (65.6%) were inside Milan, 372 (76.7%) patients were inside UCSF, 388 (80.0%) were inside MT 2.0 and 407 (83.9%) patients were inside Up-to-7; outside the criteria were 167 (34.4%), 113 (23.3%), 97 (20.0%) and 78 (16.1%) patients, respectively.

3.2. Characterization of the study cohort

There was no significant difference in basic patient demographics amongst the different HCC scoring subgroups (Table 1). As expected from the different HCC classification systems, there were significant differences in terms of size of the largest lesion and number of tumors. Patients inside Milan had a median largest lesion of 2.5 cm, compared to 4.5 cm outside Milan. Patients inside UCSF had a median largest lesion with 2.9 cm, compared to 5.0 cm outside, which was the same regarding patients evaluated according to MT 2.0. Similarly, patients inside Up-to-7 had a median largest lesion with 2.9 cm, versus 5.3 cm outside. For the whole cohort, the median largest lesion was 3.0 cm.

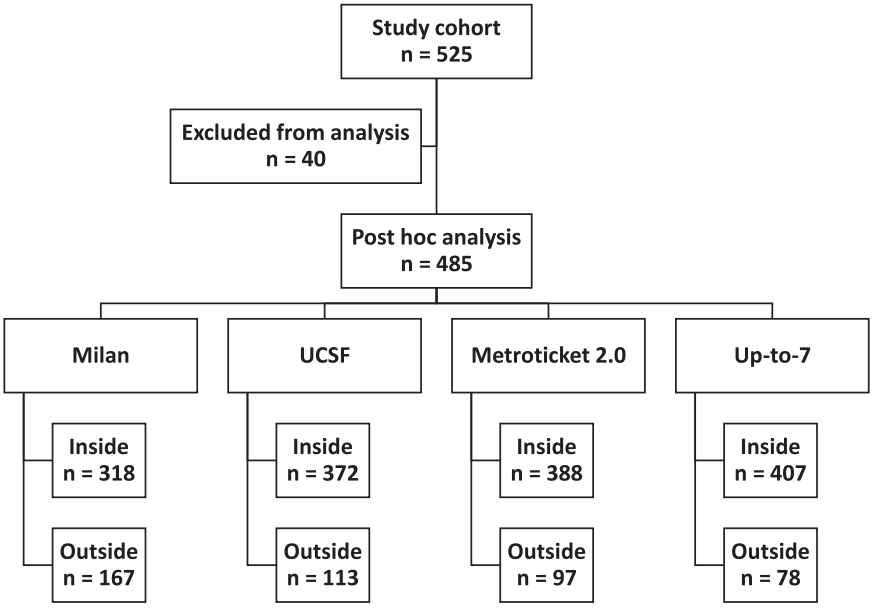

Fig. 1. Flow chart demonstrating the study cohort.

Table 1
Patient characteristics before and after classification by Milan, UCSF, MT 2.0 and Up-to-7. Groups were compared using Fisher's Exact Test or Mann-Whitney Test.

	Total		Milan	UCSF	MT 2.0	Up-to-7
Included patients, n (%)	485 (100)	**Inside**	318 (65.6)	372 (76.7)	388 (80.0)	407 (83.9)
		Outside	167 (34.4)	113 (23.3)	97 (20.0)	78 (16.1)
Age, mean years (95% CI)	57.8 (57.1 - 58.4)	**Inside**	57.5 (56.8 - 58.3)	57.9 (57.1 - 58.6)	57.7 (57.0 - 58.4)	57.7 (57.0 - 58.4)
		Outside	58.2 (57.0 - 59.3)	57.4 (55.9 - 58.9)	58.1 (56.5 - 59.6)	58.2 (56.5 - 60.0)
		p-value	0.1714	0.8248	0.4166	0.3371
Female sex, n (%)	67 (13.8)	**Inside**	49 (15.4)	53 (14.3)	57 (14.7)	58 (14.3)
		Outside	18 (10.8)	14 (12.4)	10 (10.3)	9 (11.5)
		p-value	0.1692	0.7556	0.3244	0.5952
Largest lesion, median cm (IQR)	3.0 (2.0 - 4.0)	**Inside**	2.5 (2.0 - 3.0)	2.9 (2.0 - 3.5)	2.9 (2.0 - 3.5)	2.9 (2.0 - 3.5)
		Outside	4.5 (3.5 - 6.0)	5.0 (2.5 - 6.0)	5.0 (4.0 - 7.0)	5.3 (4.5 - 7.5)
		p-value	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**
Tumor count, n (1/2/3/>3)	244/111/62/68	**Inside**	218/65/35/0	230/96/46/0	214/99/42/33	227/102/43/35
		Outside	26/46/27/68	14/15/16/68	30/12/20/35	17/9/19/33
		p-value	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**

When evaluating tumor numbers in the four patient cohorts, most inside Milan patients (218: 68.6%) had only one lesion and none (per definition) had >3 lesions; for those patients outside Milan, 26 (15.6%) had one lesion, with 68 (40.7%) having >3 lesions (Table 1). Applying UCSF criteria, the tumor size distribution was somewhat similar to the Milan criteria categorization, except these slightly more expansive criteria expectedly did result in the inclusion of more patients. In contrast, applying the MT 2.0 and Up-to-7 systems resulted in cohorts that contained substantially more tumors, as also would be predicted (patients with >3 tumors: 33; 8.5% and 35; 8.6%, respectively).

3.3. Analysis of recurrence-free survival, overall survival and freedom of tumor

In the whole study cohort, 328 (67.6%) patients achieved RFS at trial end (Table 2). For those patients within Milan criteria, 232 (73.0%) achieved RFS and a similar proportion achieved RFS within the UCSF (72.0%), MT 2.0 (71.7%) and Up-to-7 (71.0%) criteria. For OS, the four criteria gave similar 5-year rates (Milan 75.8%, UCSF 75.3%, MT 2.0 74.7% and Up-to-7 74.0%). Likewise, 5-year rates for FoT were similar (88.4%, 87.6%, 87.4% and 86.7%, respectively). As expected, patients scored as "inside" the criteria for all systems generally showed a superior RFS, OS and FoT. Corresponding Kaplan-Meier and cumulative incidence curves are shown in Fig. 2 and Supplementary Figures 1–4.

3.4. Discrimination and overall predictive performance

Accuracies shown in Table 3 were calculated by the number of patients inside a score while surviving 5 years. Discrimination of binarized scores was comparable across the four criteria and modest for all three endpoints. Harrell's C-index ranged from 0.549 to 0.566 for OS, 0.569 to 0.585 for RFS, and 0.618 to 0.639 for FoT, with Metroticket 2.0 numerically highest in each case. No pairwise difference in C-index between criteria reached statistical significance for any endpoint (all $p > 0.05$; Supplementary Table 2).

Time-dependent AUCs at every of five years showed the same pattern, with values around 0.51–0.59 for OS, 0.57–0.63 for RFS and 0.63–0.69 for FoT (Supplementary Tables 3–5). Metroticket 2.0 again had often higher AUCs, but only 4 of 90 pairwise AUC contrasts reached significance: Metroticket 2.0 versus Milan and versus Up-to-7 at 24 months for OS, and the same two comparisons at 12 months for RFS. No AUC contrast was significant for FoT. Given the absence of adjustments for multiple testing, these are interpreted as exploratory (Supplementary Table 6).

The index of prediction accuracy was uniformly low (all < 0.10 across endpoints and time points) but highest for FoT. Because

Table 2
Efficiency of classification by Milan, UCSF, MT 2.0 and Up-to-7. Groups were compared using Fisher's Exact Test.

	Total		Milan	UCSF	MT 2.0	Up-to-7
Recurrence-free survival, n (%)	328 (67.6)	**Inside**	232 (73.0)	268 (72.0)	278 (71.6)	289 (71.0)
		Outside	96 (57.5)	60 (53.1)	50 (51.5)	39 (50.0)
		p-value	**0.0007**	**0.0002**	**0.0002**	**0.0005**
Overall survival, n (%)	348 (71.8)	**Inside**	241 (75.8)	280 (75.3)	290 (74.7)	301 (74.0)
		Outside	107 (64.1)	68 (60.2)	58 (59.8)	47 (60.3)
		p-value	**0.0079**	**0.0027**	**0.0053**	**0.0191**
Freedom of tumor, n (%)	402 (82.9)	**Inside**	281 (88.4)	326 (87.6)	339 (87.4)	353 (86.7)
		Outside	121 (72.5)	76 (67.3)	63 (64.9)	49 (62.8)
		p-value	**< 0.0001**	**< 0.0001**	**< 0.0001**	**< 0.0001**

Table 3
Accuracy of classification by Milan, UCSF, MT 2.0 and Up-to-7.

	Milan	UCSF	MT 2.0	Up-to-7
Recurrence-free survival, n (%)	303 (62.5)	321 (66.2)	325 (67.0)	328 (67.6)
Overall survival, n (%)	301 (62.1)	325 (67.0)	329 (67.8)	332 (68.5)
Freedom of tumor, n (%)	327 (67.4)	363 (74.8)	373 (76.9)	382 (78.8)

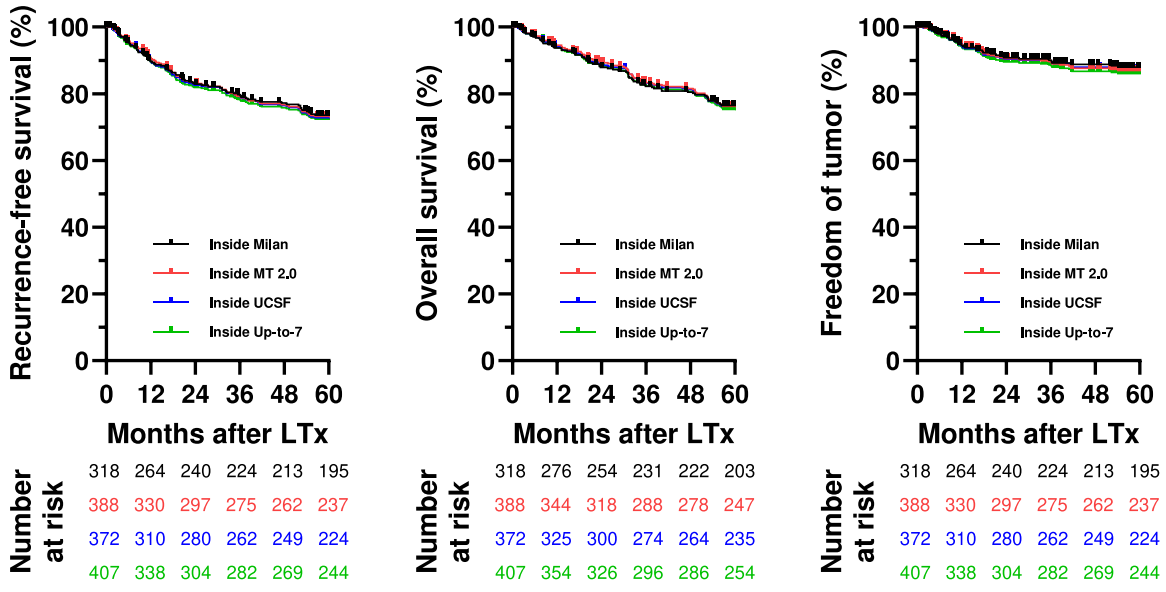

Fig. 2. Kaplan-Meier curves showing recurrence-free survival, overall survival and freedom of tumor after classification inside Milan, UCSF, MT 2.0 and Up-to-7.

each criterion yields only two predicted-risk values, the Brier score and IPA are reported as the calibration summary at every time point.

3.5. Recurrence under competing risks

In the Fine-Gray competing-risks analysis for freedom of tumour, classification outside each criterion was strongly associated with an increased subdistribution hazard of recurrence: Milan sHR 2.67 (95% CI 1.73–4.11), UCSF 3.20 (2.08–4.94), Up-to-7 3.48 (2.20–5.50) and Metroticket 2.0 3.60 (2.31–5.59), all $p < 0.001$ (Supplementary Table 7). The overlapping confidence intervals indicate that the strength of this association was similar across criteria.

4. Discussion

Results of this post-hoc analysis of the SiLVER Study data indicate that selection of eligible patients with HCC for LTx solely based on Milan criteria unnecessarily excludes potential candidates. Accordingly, patients did not have a superior outcome when categorized inside Milan criteria, compared to the other three expanded scoring systems where patients fell within the established broader criteria. This was supported by the discrimination analysis, in which C-indices were modest and showed no statistically significant differences between criteria for any endpoint, while the expanded systems classified substantially more patients (Milan 65.6%, UCSF 76.7%, MT 2.0 80.0%, Up-to-7 83.9%) as eligible.

This somewhat unexpected result could not be explained by skewed patient selection criteria in the SiLVER Study data set since Milan, UCSF, MT 2.0 and Up-to-7 cohorts did not reveal appreciable differences or bias in patient characteristics. It is notable that the SiLVER Study was an international prospectively randomized trial conducted over several years post-LTx, where patients were followed for at least 5 years, and up to 8 years, so it is unlikely that either local effects or even longer-term results would have affected outcomes with regard to survival and HCC recurrence.

There were some subtle differences in outcomes found at the extremes of the scoring systems. For instance, while patients cat-

egorized within the four systems showed similar acceptable outcomes based on C-indices and Fine-Gray subdistribution hazard ratios, patients outside Milan showed better outcomes compared to those categorized outside Up-to-7 criteria (having the worst outcomes). Therefore, pushing the boundaries of the more expansive systems clearly has limits for acceptable outcomes.

Considering the results of our analysis, perhaps national or regional guidelines based primarily on Milan criteria, such as those in the Eurotransplant region, should be reconsidered [7], bearing in mind that our data were obtained from explant histopathology. Indeed, other studies have also shown the performance of extended criteria such as UCSF and Up-to-7 not to be inferior to Milan [3,4,8–10]; adding AFP levels into decision algorithms, as in MT 2.0, can also improve accuracy [11]. The question is whether there is compelling enough evidence to change priority for more advanced HCC patients to receive a liver transplant; the results of our current analysis add valuable information to this debate.

Limitations need to be considered with regard to the SiLVER Study data used retrospectively in our current analysis. The original primary endpoint for the trial was to assess whether sirolimus-based immunosuppression improves outcomes after LTx in patients with HCC, and therefore was not designed or powered to assess LTx selection scores. Samples sizes were not calculated based on the endpoints of this post-hoc analysis and results should therefore be interpreted accordingly. Notably, since 45 sites from 13 countries were involved in the SiLVER Study, the HCC criteria used varied substantially; this explains why some patients with more extensive tumors were included in the trial, thus allowing the analysis of extended criteria we performed here, which was also supported by the assessment of explant histopathology revealing more extensive diseases in several patients than expected pre-transplant. However, combining pre-transplant imaging with post-transplant histopathology introduces a potential bias which could affect the classification inside or outside the respective score and therefore limit the clinical applicability. It is also important to note that 23 patients had to be excluded from this post-hoc analysis as at least one parameter necessary for the calculation of the scores was missing in the SiLVER data set. While our current analysis is a retrospective investigation of that dataset, with the inherent weaknesses of post-hoc studies, the SiLVER Study did offer a very substantial cohort of 485 prospectively randomized patients for study, where original pathological reports were available on all patients to confirm tumor numbers and sizes. Our conclusions are therefore limited by the retrospective approach, but are based on a highly controlled, documented and monitored set of patients with a liver transplant and HCC.

In conclusion, our post-hoc analysis of the SiLVER Study found no statistically significant differences in discrimination between the Milan, UCSF, MT 2.0 and Up-to-7 criteria across overall survival, recurrence-free survival and freedom of tumour, while the expanded systems classified substantially more patients as eligible for LTx. These results, obtained from explant histopathology, contribute to the ongoing discussion of whether Milan is optimal for selecting patients with HCC for LTx, since it may exclude eligible patients who could benefit from LTx as a treatment option.

Contributors

P.K. analysed data, drafted figures, and wrote the manuscript; **K.C.S.** analysed data; **M.H.J.W., B.J.W., L.S.K., P.K., V.M., N.B., M.A., E.K.G.** and **H.J.S.** provided clinical feedback; **G.G.** performed statistical analyses; **J.M.W.** conceived the study, analysed data, and wrote the manuscript. All authors had access to the study data and critically reviewed and approved the final version of the manuscript.

Funding

SiLVER Study was sponsored by the University Hospital Regensburg and was supported by a research grant from Pfizer Inc., Investigator Initiated Research Program (Tracking Number WS1234653). JMW received funding by grant We-4675/6–1 from the Deutsche Forschungsgemeinschaft (DFG, Bonn, Germany). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Data sharing statement

All data presented within the manuscript are available upon request from the corresponding author.

Declaration of competing interest

The authors have no conflicts of interest to declare.

Acknowledgements

The authors are grateful to all participating centers of the randomized trial and specifically thank the other members of The International SiLVER Study group: Carl Zülke, MD, Philipp E. Lamby, MD, Andrea Proneth, MD, Christophe Duvoux, MD, Patrizia Burra, MD, Karl-Walter Jauch, MD, Markus Rentsch, MD, Tom M. Ganten, MD, Jan Schmidt, MD, Utz Settmacher, MD, Michael Heise, MD, Giorgio Rossi, MD, Umberto Cillo, MD, Norman Kneteman, MD, René Adam, MD, Bart van Hoek, MD, Philippe Bachellier, MD, Philippe Wolf, MD, Lionel Rostaing, MD, Wolf O. Bechstein, MD, Magnus Rizell, MD, James Powell, MD, Ernest Hidalgo, MD, Jean Gugenheim, MD, Heiner Wolters, MD, Jens Brockmann, MD, André Roy, MD, Ingrid Mutzbauer, Angela Schlitt, MD, Susanne Beckebaum, MD, Christian Graeb, MD, Silvio Nadalin, MD, Umberto Valente, MD, Victor Sánchez Turrión, MD, Neville Jamieson, MD, Tim Scholz, MD, Michele Colledan, MD, Fred Fändrich, MD, Thomas Becker, MD, Gunnar Söderdahl, MD, Olivier Chazouillères, MD, Heikki Mäkisalo, MD, Georges-Philippe Pageaux, MD, Rudolf Steininger, MD, Thomas Soliman, MD, Koert P. de Jong, MD, Jacques Pirenne, MD, Raimund Margreiter, MD, Johann Pratschke, MD, Antonio D. Pinna, MD, Johann Hauss, MD, Stefan Schreiber, MD, Simone Strasser, MD, Jürgen Klempnauer, MD, Roberto I. Troisi, MD, Sherrie Bhoori, MD, Jan Lerut, MD, Itxarone Bilbao, MD, Christian G. Klein, MD, Alfred Königsrainer, MD, Gerd Otto, MD, Vincenzo Mazzaferro, MD, and Peter Neuhaus, MD.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.dld.2026.07.082.

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