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NATIONAL POLICY UPDATES FOR LIVER TRANSPLANTATION (LT) FOR HEPATOCELLULAR CARCINOMA (HCC)

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DISCLAIMER

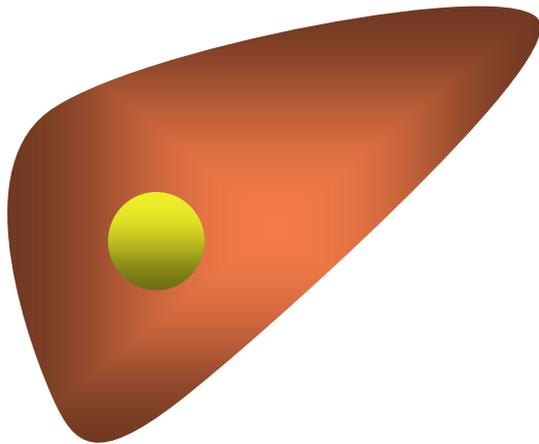
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This content is supported by an Independent Educational Grant from Bayer.

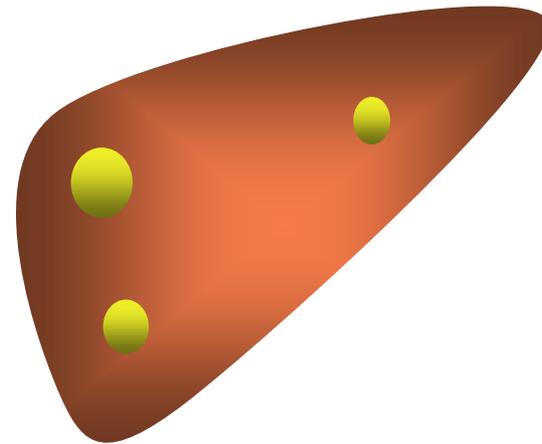
LIVER TRANSPLANTATION FOR HCC

MILAN CRITERIA

1 lesion ≤ 5 cm



2 to 3, none > 3 cm



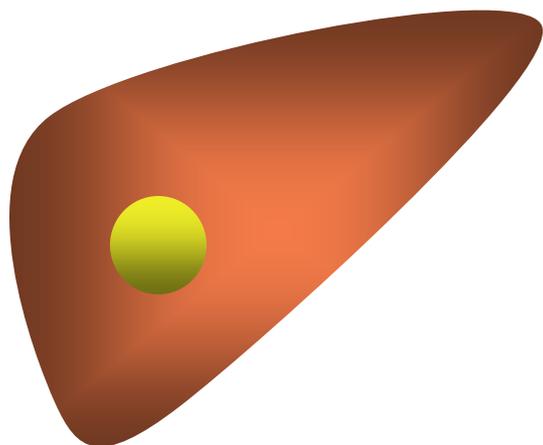
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Absence of Macroscopic Vascular Invasion
Absence of Extra-hepatic Spread

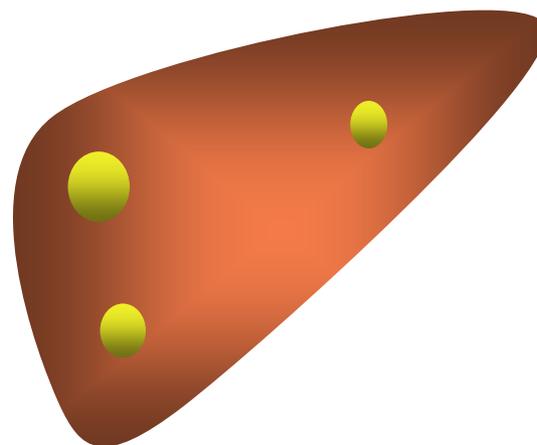
LIVER TRANSPLANTATION FOR HCC

MILAN CRITERIA

1 lesion \leq 5 cm



2 to 3, none $>$ 3 cm



Post-LT

5-year survival: $>$ 75%

5-year HCC recurrence: 10–15%

LIVER TRANSPLANTATION FOR HCC

RECENT CHANGES

Uniform diagnostic criteria (OPTN/ LIRADS) + standardised reporting

- Only HCC patients within Milan criteria with LIRADS 5 lesions are eligible to receive priority listing

LIVER TRANSPLANTATION FOR HCC

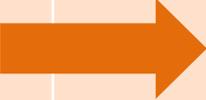
RECENT CHANGES

Uniform diagnostic criteria (OPTN/ LIRADS) + standardised reporting

- Only HCC patients within Milan criteria with LIRADS 5 lesions are eligible to receive priority listing

6-month mandatory waiting period before awarding MELD exception

DELAYED HCC-MELD EXCEPTION SCORE

| Delays in HCC-MELD exception | HCC LT rates (per 100 person-years) | Non-HCC LT rates (per 100 person-years) |
|--|--|--|
| 0 | 108.7 | 30.1 |
| 3 months | 65.0 | 32.5 |
| 6 months  | 44.2 | 33.9 |
| 9 months | 33.6 | 34.8 |

LIVER TRANSPLANTATION FOR HCC

RECENT CHANGES

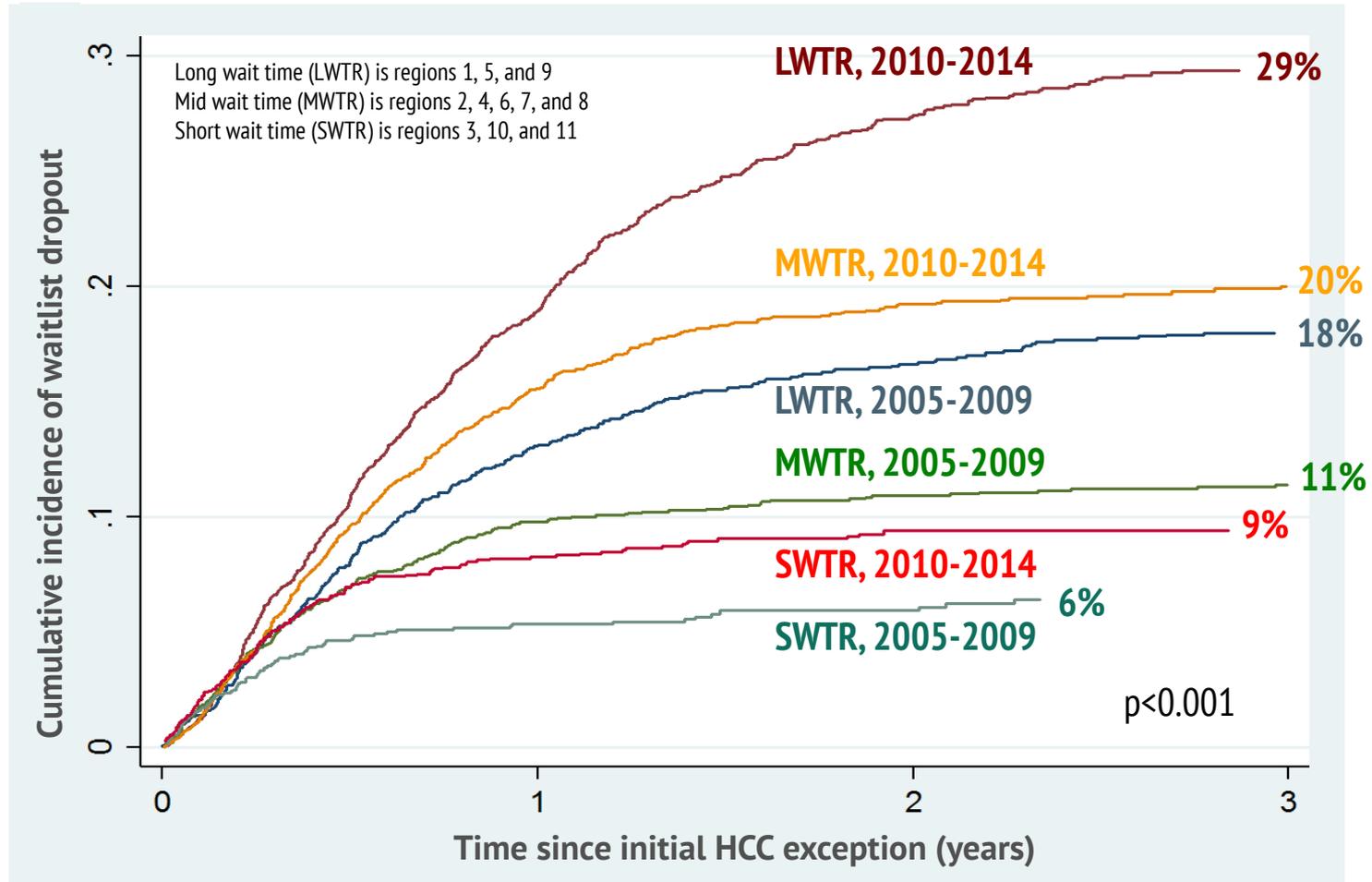
Uniform diagnostic criteria (OPTN/ LIRADS) + standardised reporting

- Only HCC patients within Milan criteria with LIRADS 5 lesions are eligible to receive priority listing

6-month mandatory waiting period before awarding MELD exception

Regional variation in access to LT for HCC still exists

PROBABILITY OF WAITLIST DROPOUT BY WAIT TIME REGION AND LISTING PERIOD



LIVER TRANSPLANTATION FOR HCC

RECENT CHANGES

Uniform diagnostic criteria (OPTN/ LIRADS) + standardised reporting

- Only HCC patients within Milan criteria with LIRADS 5 lesions are eligible to receive priority listing

As of May 2019, the HCC-MELD ladder system has been replaced by awarding median MELD at transplant (MMAT) for the donor service area (DSA) minus 3 points

- 6-month waiting period still in effect

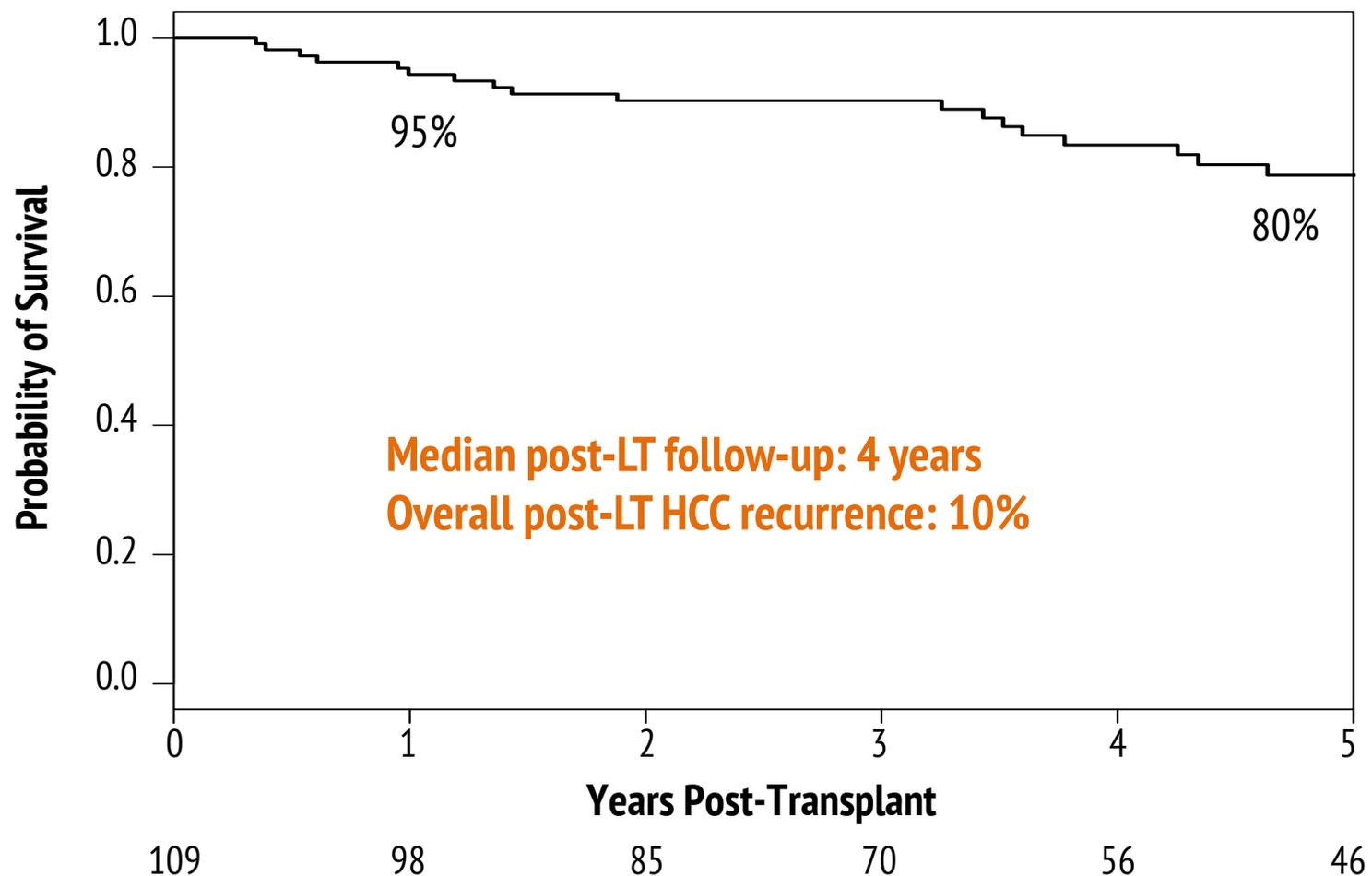
6-month mandatory waiting period before awarding MELD exception

Regional variation in access to LT for HCC still exists

DOWN-STAGING OF HCC FOR TRANSPLANT

- **Definition:** Reduction in the tumour size using local regional therapy to meet acceptable criteria for LT¹
- **Tumour response:** Based on radiographic measurement of the size of all viable tumours, not including the area of necrosis from local regional therapy²
- **A selection tool** for tumours with more favourable biology that respond to down-staging treatment and do well after LT¹

REGION 5 MULTI-CENTRE DOWN-STAGING STUDY: POST-LT SURVIVAL



UNOS DOWN-STAGING PROTOCOL

- **Inclusion criteria**

- 1 lesion >5 cm and ≤ 8 cm
 - 2 or 3 lesions ≤ 5 cm with total tumour diameter ≤ 8 cm
 - 4 or 5 lesions ≤ 3 cm with total tumour diameter ≤ 8 cm
 - No vascular invasion on imaging
-
- This protocol has recently been adopted as national policy for automatic priority listing in patients who have been successfully down staged to within Milan criteria

RECENT UNOS POLICY CHANGE

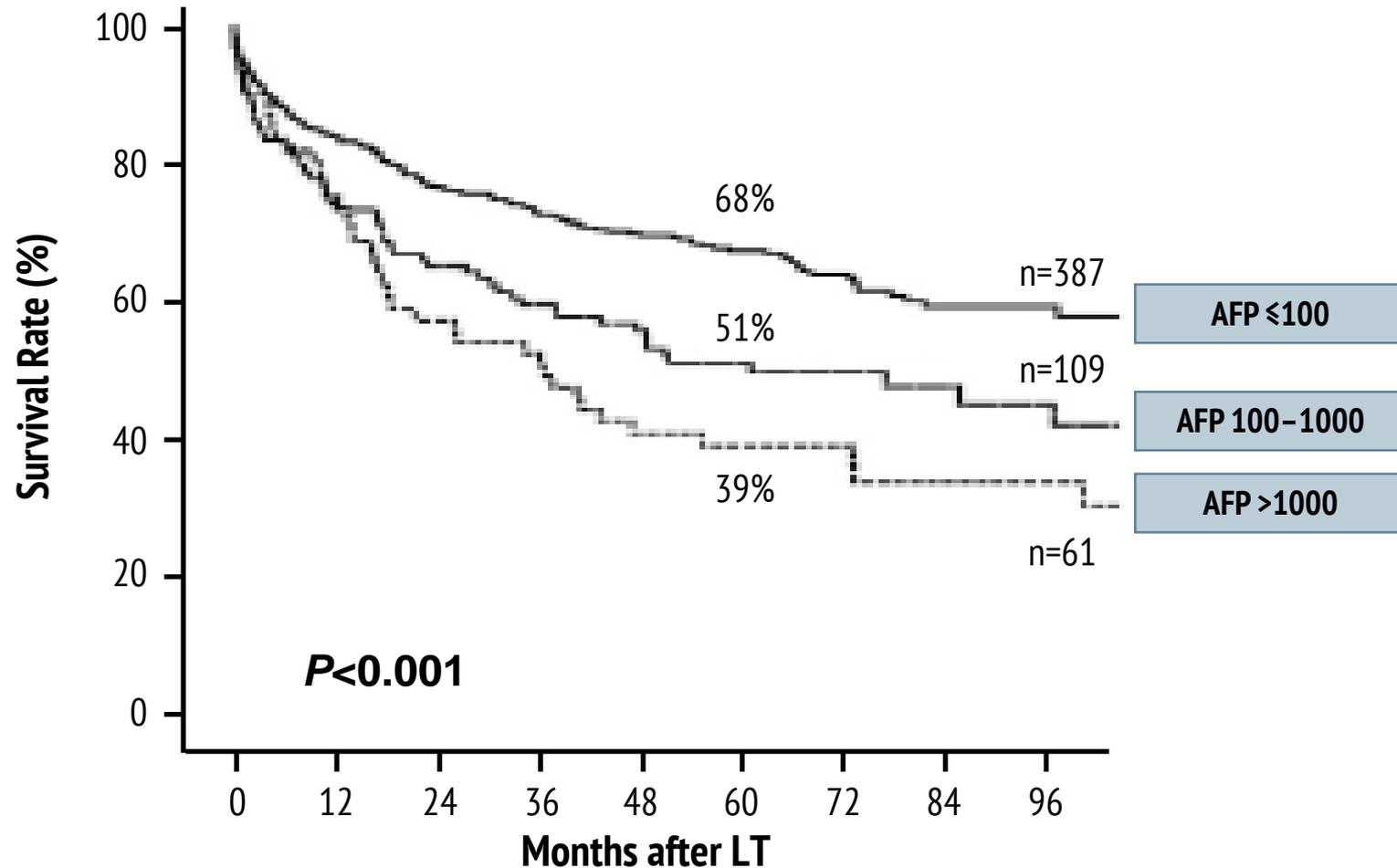
High AFP Threshold

- Candidates with lesions meeting T2 criteria but with an AFP >1000 are not eligible for a standardized MELD exception
- If AFP falls <500 after local regional therapy, the candidate is eligible for a standardized MELD exception

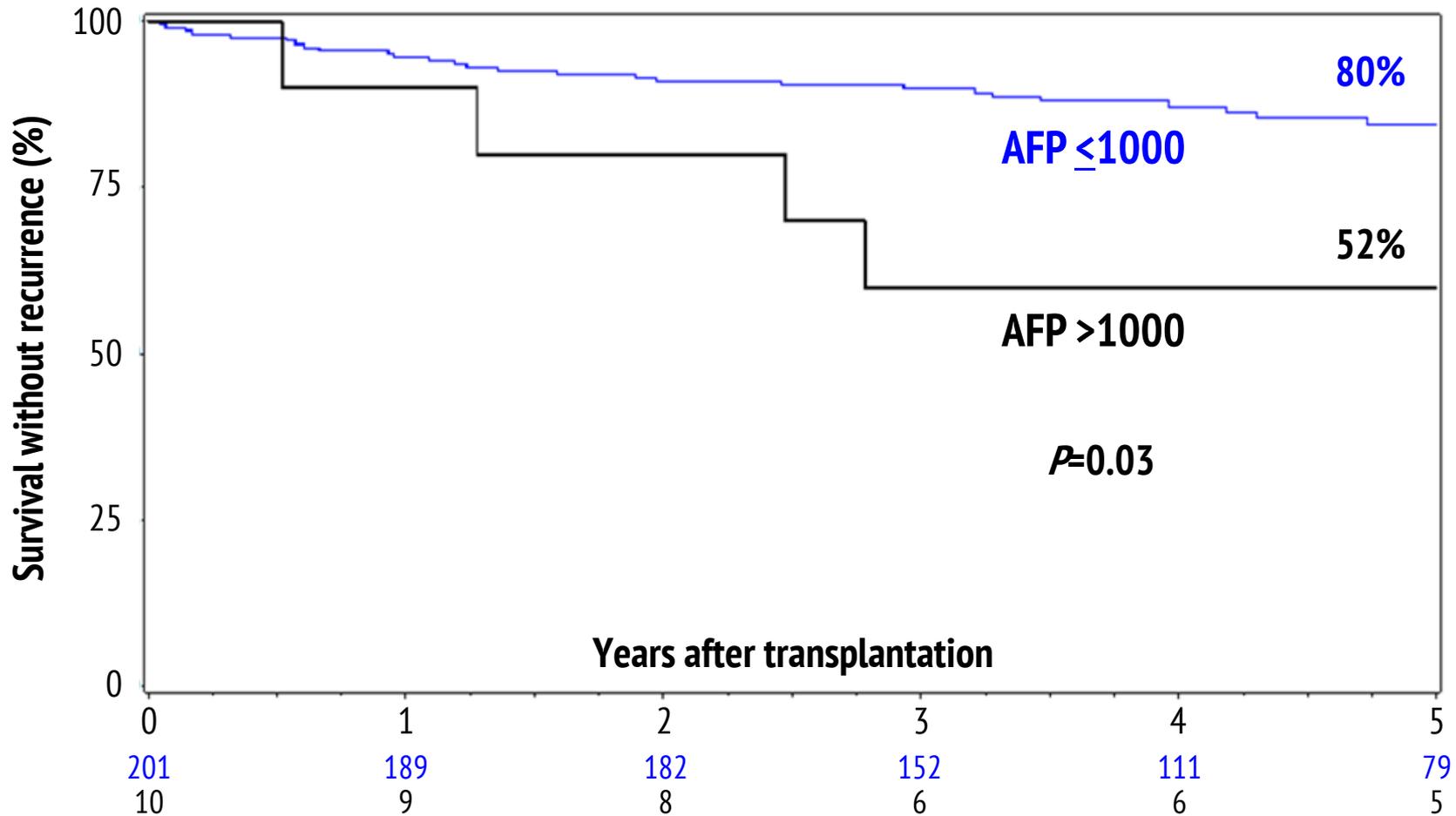
AFP, alpha-fetoprotein; MELD, Model for End-Stage Liver Disease; UNOS, United Network for Organ Sharing

1. Hameed B, et al. *Liver Transplantation*. 2014;20:945-951. 2. OPTN/UNOS Policy Notice Modification to Hepatocellular Carcinoma (HCC) Extension Criteria. Available at: https://optn.transplant.hrsa.gov/media/2411/modification-to-hcc-auto-approval-criteria_policy-notice.pdf. Accessed 28 August 2019.

AFP AND POST-TRANSPLANT OUTCOME FRANCE



AFP AND POST-TRANSPLANT OUTCOME – UCSF



SUMMARY

- After **6-month delay**, eligible HCC patients are now awarded **MMAT-3** rather than the previous ladder upgrade system
- Patients within UNOS down-staging criteria who are **down-staged into Milan criteria** with local regional therapy are eligible for **automatic priority listing**
- **Patients with AFP ever >1000 must come down to <500** with local regional therapy before being eligible for LT

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