

Effect of Mandatory 6-Month Waiting Period on Waitlist and Transplant Outcomes in Patients With Hepatocellular Carcinoma

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BACKGROUND AND AIMS: Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) policy mandates a 6-month waiting period before exception scores are granted to liver transplant candidates with hepatocellular carcinoma (HCC). This study aims to evaluate waitlist and posttransplant outcomes in patients with HCC, before and after implementation of the 6-month waiting rule.

APPROACH AND RESULTS: We examined two groups from the UNOS registry: Group 1 (pre-6-month rule) consisted of patients registered as transplant candidates with HCC from January 1, 2013, to October 7, 2015 (n = 4,814); group 2 (post-6-month rule) consisted of patients registered from October 8, 2015, to June 30, 2018 (n = 3,287). As expected, the transplant probability was higher in the first 6 months after listing in group 1 than group 2 at 42.0% versus 6.3% ($P < 0.001$). However, the 6-month waitlist mortality/dropout rate was lower in group 2 at 1.2% than group 1 at 4.1% ($P < 0.001$). To assess regional parity of transplant, UNOS regions were categorized into three groups based on Model for End-Stage Liver Disease score at transplant: lower-score (regions 3, 10, and 11), middle-score (1, 2, 6, 8, and 9), and higher-score region groups (4, 5, and 7). Outcomes were compared from the time exception points were given, which we defined as conditional waitlist outcomes. Conditional waitlist mortality/dropout decreased, and transplant probability increased in all region groups, but the benefits of the policy were more pronounced in the higher and middle-score groups, compared with the lower-score group. The decline in waitlist

mortality/dropout was only significant in the high Model for End-Stage Liver Disease group ($P < 0.001$). No effect was observed on posttransplant mortality or percent of patients within Milan criteria on explant.

CONCLUSIONS: The HCC policy change was associated with decreased waitlist mortality/dropout and increased transplant probability. The policy helped to decrease but did not eliminate regional disparities in transplant opportunity without an effect on posttransplant outcomes. (HEPATOLOGY 2020;72:2051-2062).

Liver transplantation is an established treatment option for hepatocellular carcinoma (HCC). In the United States, donated livers are allocated using the Model for End-Stage Liver Disease–Sodium (MELD–Na) score, which predicts 90-day mortality. Because patients with HCC often have low laboratory MELD–Na scores that do not reflect their mortality from cancer spread, Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) policy assigns an exception score to more accurately reflect true mortality.⁽¹⁻⁴⁾ Since 2005, patients with T2 lesions had been given an exception score of 22, which would increase an additional 3 points every 3 months.⁽⁵⁾ In 2015, this

Abbreviations: aHR, adjusted hazard ratio; AFP, alpha-fetoprotein; CI, confidence interval; HCC, hepatocellular carcinoma; IQR, interquartile range; MELD, Model for End-Stage Liver Disease; MELD–Na, Model for End-Stage Liver Disease–Sodium; OPTN, Organ Procurement and Transplantation Network; TACE, transcatheter arterial chemoembolization; UNOS, United Network for Organ Sharing.

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Potential conflict of interest: Dr. Salgia is on the speakers' bureau for Eisai, Bristol–Myers Squibb, and Exelixis.