Growing number of patients who might benefit from liver transplant removed from wait list

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The sickest liver transplant candidates should be first in line when a donor liver becomes available, but transplant centers are increasingly removing these individuals from the waiting list, considering them "too sick to transplant," an analysis of nationwide transplant data finds. The study appears online as an "article in press" on the *Journal of the American College of Surgeons* website in advance of print publication.

Between mid-2007 and 2012, more than 4,300 Americans with life-threatening liver diseases were taken off the transplant waiting list, or "delisted," because of deteriorating illness as determined by their transplant center, study authors reported. That number was nearly twice the 2,311 liver transplant candidates delisted between April 2002 and June 2007 because of reported illness severity.

"The central tenet of liver transplant allocation is to prioritize the sickest patients first," said the study's senior investigator Adel Bozorgzadeh, MD, FACS, a transplant surgeon at UMass Memorial Medical Center in Worcester, Mass. "Yet, more and more patients who could potentially benefit from a liver transplant are being denied this lifesaving procedure."

Nearly 14,750 liver transplant candidates are currently on the U.S. transplant waiting list, the Organ Procurement and Transplantation Network[1] reports.

In deciding when to remove individuals from the transplant waiting list, liver transplant teams primarily use their clinical judgment, according to Dr. Bozorgzadeh. An exception is patients with liver cancer, for whom objective measures of tumor progression are used to determine medical unsuitability for transplantation. Although there are valid reasons why someone might be too ill to undergo liver transplantation, he said the noticeable increase in the number of delisted patients due to worsening health suggests other factors are playing a role.

Lead study author Natasha Dolgin, PhD, of the University of Massachusetts Medical School, Worcester, said she initiated this study as a student in the university's MD/PhD program after noticing climbing waiting list removal rates in recent years.

In 2007 the Centers for Medicare and Medicaid (CMS) began a new regulatory policy, called Conditions of Participation, or CoP. According to CMS, the policy established expectations for safe, high-quality transplant services in Medicare-participating facilities.

Although transplant centers' outcomes have been publicly reported for years, under the new policy the outcomes reports were used for the first time to label transplant centers as "good" or "bad" performers, Dr. Dolgin said. There also are potential consequences for centers that perform below the new CMS-defined benchmarks for volume of transplant procedures and one-year survival rates for both the patient and the transplanted organ. If the centers do not meet the required conditions, they could lose Medicare funding and coverage by private insurers, and face closure.

Dr. Dolgin and coauthors wondered what impact the CoP policy had on liver transplant centers' waiting lists nationally. They studied trends in delisting rates and one-year post-transplant mortality, or death rates, for 90,765 adults awaiting a liver from a deceased donor from April 2002

through December 2012 at 102 liver transplant centers. The researchers compared trends during the five years before versus after CoP implementation. They did not include patients with liver cancer. Data came from the Scientific Registry of Transplant Recipients, the national database of transplant statistics.

Importantly, the investigators found that the CoP policy was not associated with a significant improvement in one-year post-transplant death rates. The one-year patient survival rate, they discovered, rose only slightly, from 86.6 percent before CoP implementation to 88.5 percent after implementation.

"Although the CoP policy was a quality improvement initiative designed to improve transplant patient outcomes, in reality, it failed to show beneficial effects in the liver transplant population," Dr. Dolgin said.

The investigators found that immediately after CoP implementation, there was a 16 percent spike in liver transplant candidate delisting because of patients becoming "too sick for transplant" or "medically unsuitable." The likelihood of delisting continued to increase by 3 percent per quarter through the end of the study according to the researchers. They reported that, on average, there was one delisting for every nine transplants in the years before CoP implementation, but that ratio rose to 1:5 after implementation.

Dr. Dolgin and her colleagues speculate that changes in waiting list management are occurring because the CoP unintentionally influenced transplant centers—especially those flagged by CMS for underperformance—to become more averse to risk. For example, critically ill patients requiring artificial life support have an increased risk of death after transplantation, but prior studies[2] have found the sickest patients derive the greatest survival benefit from a transplant.

Transplant teams should weigh the risk of death after transplantation against the patient's risk of death without a transplant, the researchers recommended.

However, CMS considers death rates only in transplant recipients, not in candidates who do not receive a transplant, Dr. Dolgin noted. She called for future transplant research and policy decisions that balance improving survival rates after liver transplantation with survival rates for transplant candidates.

Meanwhile, Dr. Bozorgzadeh suggested that liver transplant candidates should ask their surgeon: What percentage of the patients you add to your center's waiting list do you transplant? What are your criteria for too sick to transplant that would result in my removal from the list?

More information: Decade-Long Trends in Liver Transplant Waitlist Removal due to Illness Severity: The Impact of Centers for Medicare and Medicaid Policy, *Journal of the American College of Surgeons*.

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