

TRANSPLANTATION OF HEPATITIS C-VIREMIC DONOR ORGANS INTO HEPATITIS C UNINFECTED RECIPIENTS

The growing gap between the number of individuals waiting for an organ transplant and the number of organs available is a crisis worldwide. The transplant community must explore opportunities for expanding access to this life enhancing and often lifesaving procedure. With the development of therapies to effectively cure hepatitis C (HCV) infection, the utilization of organs from HCV-viremic donors into HCV-uninfected recipients as a prospect for increasing the number of transplants is a possible option. Recognizing the potential, the AST held a consensus conference on this topic in January 2017 to encourage ongoing research in this important area¹.

Historically, HCV-viremic donor livers and kidneys were transplanted into HCV-viremic recipients. However, the number of HCV-viremic candidates on organ transplant waiting lists has decreased due to the widespread use of highly effective directly acting antiviral (DAA) therapy. As a result, organs from HCV-viremic donors, are at risk for being discarded, while uninfected patients with end organ failure remain at risk of dying on the waiting list. In recent years, studies from several institutions in the United States demonstrated that organs from HCV-viremic donors can be safely transplanted into uninfected, kidney, liver, heart and lung recipients, with commencement of DAA therapy at the time of, or shortly after transplant surgery. Although transmission of HCV infection via transplantation is invariable, cure rates with DAA therapy in this population have been over 98%; the few cases of treatment failure have occurred predominantly when there have been delays with DAA therapy initiation. The longest published follow up is in kidney transplant patients, with similar 12-month outcomes between recipients of organs from HCV-viremic and HCV-negative donors. Delays in, or inability to obtain insurance approval for DAA therapy post-transplant have been identified as barriers to expanding this practice and thus ensuring that all organ transplant candidates have access to organs from HCV-viremic donors.

The American Society of Transplantation (AST) is supportive of both ongoing research and advancement of clinical practice that focuses on safely transplanting organs from HCV-viremic donors into HCV-negative recipients. Careful consideration of candidates and ongoing research should be performed by multidisciplinary transplant teams of experts comprising the primary organ specialist, hepatology, infectious disease physicians and transplant pharmacy. This consideration should include removal of barriers to insurance coverage for post-transplant DAA therapy that could directly stratify and limit access to transplant healthcare, and potentially jeopardize the ongoing establishment of a new standard of care. Based on the available data, the AST believes that failure to pay for DAA therapy disadvantages HCV-negative transplant candidates who would be eligible to receive organs from HCV-viremic donors, while delays in approving DAA coverage increase the risk of acute HCV-related complications in the recipient, thereby mitigating the potential advantage of this approach.

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¹ Levitsky J, et al. *Am J Transplant* 2017; 17(11): 2790-2802.