The “increased-risk donor”: A plea for redefinition

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Central Message

The majority of “IR” organ donors are, in reality, not high risk as long as current testing methods for HIV and HCV do not identify circulating virus.

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Shudo and colleagues¹ have provided an important service to the thoracic transplant community with this excellent analysis highlighting the good outcomes achieved with the Centers for Disease Control (CDC) increased-risk (IR) donors, the criteria for which were established in 2004. Using a nicely designed propensity score matching model, they have documented equivalent survival to non-IR donors. Those knowledgeable within the transplant community find this as no surprise, because these are typically donors with otherwise robust heart function. They are labeled “high risk” because of a lifestyle that brought them into contact with individuals likely to be infected with the human immunodeficiency virus (HIV) or hepatitis C virus (HCV). This has historical significance, since in 2004 the basic screening tests for HIV and HCV were serologic assays based on antibody detection. The well-recognized dilemma was the window of up to 6 months between the time of exposure/infection and the development of antibodies (detection). “The window” represented a major challenge in organ allocation, because a negative serology provided no confidence that a donor with a history of high-risk behavior was not actually infected. Therefore, for the next decade after the CDC created the category of “IR” donors, most centers would not accept such donors for transplantation, regardless of serology results.

Over the past several years, nucleic acid amplification testing (NAT) for both HIV and HCV has become a routine part of donor screening in most centers. This highly sensitive assay detects HCV or HIV RNA genetic material in serum or plasma soon after infection with these viruses. In a report posted on the National Institutes of Health Library of Medicine website (ClinicalTrials.gov) in March of 2000, an ongoing NAT screening study was reported, in which it was anticipated that “NAT screening will reduce the risk of transfusion-related HIV transmission from the current 1 in 650,000 to 1 in a million and the risk of HCV transmission from the current 1 in 100,000 to 1 in 350,000. It is possible that these tests will completely eliminate the risk of transmitting these diseases through blood

transfusion.” In May of 2013, the CDC posted a recommendation for the use of the Food and Drug Administration–approved NAT assay for HIV and HCV screening (www.cdc.gov/mmwr). With the routine application of NAT testing to potential organ donors, we have entered a new era in which among donors at high risk for HIV/HCV infection (and other donors as well), the transplant team can be confident that a negative NAT assay confers an extremely high likelihood that the donor is not infected with HIV or HCV.

With articles like this extolling the safety of using CDC high-risk donors, the authors bring attention to the misnomer of the label “IR donors.” In the current era, these donors in all likelihood are actually “normal risk” from an infection perspective if the NAT test results are negative. Current knowledge about NAT testing should stimulate a plan to routinely incorporate NAT results in all large transplant databases such as the United Network for Organ Sharing, correlated with follow-up information about recipient conversion rates. The test hypothesis would be that “NAT-negative IR donors are no more likely to transmit HIV or HCV than non-IR NAT-negative donors.” If this can be established, it would seem appropriate to remove the label of “IR” from the group of current IR donors with high-risk behavior who test negative by NAT for both HCV and HIV.

So, the real message here is that, as defined by the CDC in 2004, the majority of the “IR” donors are, in reality, not high risk if their NAT test results are negative. With some additional analyses, the CDC should revisit the current IR

definition. The authors are to be congratulated for again bringing this issue to the forefront of the “donor-recipient” conversation.

Reference

1. Shudo Y, Cohen JE, Lingala B, He H, Zhu Y, Woo J. Impact of “increased-risk” donor hearts on transplant outcomes: a propensity matched analysis. *J Thorac Cardiovasc Surg*. 2019;157:603-10.