Virally Infected Donor Grafts

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The ideal management for end stage liver disease, acute liver failure, and hepatocellular carcinoma (HCC), within specific criteria, is liver transplantation (LT). Due to continuous increase in LT cases, there has been consideration to increase utilization of organs from donor livers which were previously discarded, including virally infected donor livers.

Keywords: liver transplantation ; HIV ; HCV ; HBV

1. HIV

The first HIV liver transplant conducted by Nor et al. was done in the pre HCV direct acting antiviral (DAA) era. In that study and many other studies of the same era, good short-term outcomes were seen in pure HIV candidates, but patient/graft survival was significantly decreased by the presence of HCV, either as mono infection or combined with HIV [1][2]. Post LT mortality using HIV positive donors was reduced considerably when DAA's efficacy of almost 100% managed HCV infections both pre and post-transplant [3]. This promising change along with the fact that there has been a global shortage of liver donors, prompted researchers to study HIV positive donor LT vigorously. A study was conducted in 2010 where Dr. Elmi Muller launched HIV positive donor kidney transplants in South Africa [4]. His prospective, nonrandomized study included 27 HIV positive recipients who were followed for a median of 27 months. The 1- and 5-year survival were similar to HIV negative controls at the center (84% vs. 91% and 74% vs. 85%, respectively). Rejection rates were 8% at 1 year and 22% at 3 years [4]. Immunosuppressants used in this study included induction therapy with anti–T-cell antibody and maintenance therapy with tacrolimus, mycophenolate mofetil, and glucocorticoids [4] In another set of studies conducted in Europe, it was shown that with the use of HAART (Highly Active Anti-Retroviral Treatment), HIV could fully be brought under control post-transplant [5]. Results from such studies against a background of soaring organ shortage led to the passing of the HIV Organ Policy Equity (HOPE) Act (passed in 2013 in the USA) which was a breakthrough in the field of transplantation [6]. It allowed HIV positive donors to offer grafts to HIV positive recipients. Calmy et al. reported one of the early successful LT in Switzerland in 2015, where a 53-years-old HIV positive was successfully transplanted from an HIV positive donor [5]. The crucial part was played by antiretrovirals post LT, which helped to maintain undetectable HIV RNA with no graft rejection. A steroid-free immunosuppressive regimen including basiliximab induction, as well as tacrolimus and mycophenolate mofetil was used in this study [5]. From 2016, encouraging results from John Hopkins was reported for HIV positive donor to HIV positive recipient transplantation [7]. A longitudinal study done recently as a part of HOPE pilot trial followed HIV positive recipients who had received HIV positive donor liver and kidney grafts. After 3 years of follow up, no evidence of donor derived HIV superinfection was detected in any of the recipients, including one who had temporarily stopped the HAART therapy [8]. Another survey was done on 209 transplant centers to study center level barriers in implementation, knowledge, attitudes, and planned HIV positive donor protocols [8]. It was deduced that most centers (91.2%) were aware of the legality of HIV positive donor transplantation while 21.4% were oblivious to HIV related guidelines. Furthermore, most centers (83.2%) stood in favor of HIV positive donor liver transplantation. However, they believed the willingness of their HIV positive candidates to accept grafts from HIV positive donor organs could be an issue ($p < 0.001$) [8]. Other factors on top of the HOPE protocol that could determine HIV positive donor transplants were: degree of endemicity of HIV in an area, HIV positive recipient load, and total transplant load [8]. Thus, the HOPE Act made it possible for the implementation of transplantation of HIV positive donors into HIV positive recipients, which would have otherwise been rejected. The HOPE Act also stipulated for the efficient utilization of organs that were earlier claimed to be HIV positive and discarded but actually were only false positives. The Action Trial of HOPE identified certain patients who showed positive HIV serology or NAT (Nucleic Acid Testing), but never had an infection. These were classified as false positives and 10 such patients were identified in the study. From these 10 suspected false positives, 21 HIV positive recipients received transplants. Later, all the donors were found to be uninfected. The American Society of Transplantation has also issued guidelines for HIV positive recipients who not only suffer from higher wait list mortality but decreased access to transplantation as well. Even though more data is emerging in support of utilization of HIV positive donors in HIV positive recipients, it is still not advisable to use HIV positive allografts in HIV negative recipients as HIV can only be controlled and not cured. In 2017, in Africa, there was an emergency LT for a life-threatening

state wherein an HIV negative child received a graft from his mother who was HIV positive. More than a year following LT, no viremia has been reported in the recipient child [9]. Even though the overall results look promising, differences between HIV infections in Africa vs. the US should be kept in mind. Differences in terms of HIV sub type, exposure to HAART, and prevalence of HAART resistance are critical determining factors for HIV positive donor LT outcomes. Thus, more data is needed in support of such transplantation in life saving situations.

2. HCV

An estimated 300 to 500 additional liver allografts from HCV positive donors could be utilized for transplantation to maximize liver donor pool [10]. Increasing intra venous opioid consumption in society has not only led to a greater incidence of HCV but also overdose related deaths [11]. The US opioid epidemic continues to increase, and deaths from opioid misuse increased threefold between 1999 and 2014 [12]. This unfortunate event has, however led to an increase in successful incorporation of HCV positive donor liver allografts in the donor pool due to availability of effective DAA's [13][14]. Therefore, shifting the spotlight on making HCV positive donor liver allografts as efficient as possible for LT is the need of the hour so it can help us deal with the organ shortage. In 2015, the United Network for Organ Sharing (UNOS) made NAT a compulsory test along with serology in donors. Both NAT and serology positive (viremic, sero positives) suggest active infection, which has high infectivity, whereas only NAT positive (viremic, sero negatives) indicates a window period that also has considerable infectivity. A positive serology only (nonviremic, sero positive) could mean either a treated/cleared HCV infection or a false positive. The infection risk for pure sero positive ranges between 0% to 16%, whereas in viremic it is almost 100% [15]. The introduction of DAAs has improved LT outcomes because of increased sustained virologic response and fewer adverse effects. The use of the HCV viremic organ for an HCV negative recipient requires the recipient to have prompt posttransplant access to pan genotypic DAA treatment, and preemptive therapy is recommended [16]. Study by Northup et al. on 934 HCV positive donors suggested that HCV positive liver donors showed no increased mortality risk in HCV positive recipients compared to HCV negative liver donors [17]. Similarly, Ting et al. published results from a cohort of 26 HCV sero negative recipients of HCV seropositive donor grafts followed by preemptive DAA regimen, defined as the initiation of DAA after the first positive HCV NAT in LT recipient (median 5.3 weeks after LT) [14]. All 12 recipients completing their DAA regimen and reaching sufficient follow up achieved sustained virological response. Out of the 12 recipients who achieved sustained virological response, 1 received Ledipasvir/Sofosbuvir for 12 weeks, 1 received Sofosbuvir/Velpatasvir for 8 days, followed by Ledipasvir/Sofosbuvir for 23 weeks, and 10 recipients were treated with Glecaprevir/Pibrentasvir for 12 weeks [14]. While researchers have an established DAA protocol pre/post-transplant for the former, a proper protocol for the latter is awaited. The timing and duration of DAA treatment are variable among centers. Studies are being conducted, and one involving Kidney Transplants from HCV positive donors into HCV negative recipients have shown promising results wherein 19 such recipients on getting the graft underwent DAA treatment regime for post-transplant viremia and showed complete sustained virological response [18]. In the study by Novak et al. 21 HCV negative recipients were transplanted with HCV (nonviremic, sero positive) positive kidney grafts, none showed NAT positive on follow up and had a survival rate of five years [19]. Also, considering that HCV is now a curable disease, using HCV positive donor grafts in HCV negative recipients seems plausible, especially in the setting of organ shortage. A recent publication from Cotter et al., after reviewing Scientific Registry of Transplant Recipients database has shown that only 87 HCV positive to HCV negative transplants were done before January 2018 and they showed similar 2 years survival outcome as for recipients of HCV negative donors [20]. Minimizing other graft limiting factors affecting the transplant outcomes, from HCV positive donor, may further improve the success rate. One such factor being allograft fibrosis for which an algorithm was suggested in a study. It showed that the stage of hepatic fibrosis in NAT positive donors further determined the suitability of using the graft. On biopsy (done after NAT was positive), liver fibrosis greater than Stage 2 rendered the graft to be declined considering significant allograft fibrosis [21]. A recent meeting consensus report has recommended that young HCV viremic donors (<35 y of age) are likely to have minimal fibrosis and do not require pre donation liver biopsy, and can have a surgical assessment at the time of organ procurement to determine if a liver biopsy is indicated. Older HCV viremic donors (≥35 y of age) with chronic infection should undergo a liver biopsy to exclude those with advanced (F3 or F4) fibrosis. Mild fibrosis (F2 or lower) is acceptable for transplantation [16].

Another modifiable marginal factor is the donor age. With an, unfortunately, higher incidence of opioid overdose deaths, liver grafts are now coming from younger donors, since opioid use is more common in this age group [22]. Hence, close post-transplant follows up coupled with the immediate commencement of DAA as soon as HCV is detected is the best strategy that can not only ensure successful utilization of HCV grafts but also deal with a rare, yet severe complication of HCV, namely fibrosing cholestatic hepatitis which can cause rapid graft failure. DAA regimen has significantly improved the management of HCV even in post-transplant and immunocompromised states. This has made use of HCV positive grafts much more acceptable and even greater than that of HBV and HIV positive donor grafts. Unlike HCV, latter

diseases can only be suppressed and not cured. Despite DAA's efficacy in the face of HCV positive donor transplant, some patients who do not have a very high MELD score are not treated with DAA. This is because getting cured from HCV post DAA therapy causes a reduction in their MELD score which takes away their eligibility status for a transplant. Such a category is often called MELD purgatory. HCV positive donor grafts can specifically be used in the case of MELD purgatory patients with decompensation who even though are deemed 'too fit' for a transplant due to a low MELD score, can get an HCV positive donor graft to improve their quality of life. Even though more evidence is in favor of HCV positive donor grafts, some of the challenges are unwillingness of patients to receive an HCV positive graft, ethical problems especially when viewing the scenario as a conscious transference of infection in a patient and cost factors/insurance coverage for DAA. Despite the challenges, using HCV positive donor grafts is a plausible option now being used in most transplant centers.

3. HBV

Around 0.24 billion people in the world are positive for hepatitis B surface antigen (HBsAg) [23]. In the current era, using hepatitis B immune globulin (HBIG) and antivirals post transplantation has decreased the incidences for recurrence of HBV and improved overall survival [24]. Nonetheless, the transmission of infection is a major concern, and it has not only been reported for hepatitis B surface antigen (HBsAg) positive donors but also for liver donors who were negative for HbsAg but anti-hepatitis B core antigen (anti Hbc) positive. HBcAb positive donors can have covalently closed circular DNA (cccDNA) retained inside hepatocytes leading to risk for HBV transmission. Historically, the first HBV positive donor graft was done in pre-antiviral era on a child in need of an emergent liver transplant for a life-threatening condition. Several months later, the child tested positive for HBV which was taken care by lowering his dose of immunosuppressant drugs and using ciprofloxacin along until he tested negative [25]. A systematic review including 39 studies reported considerably lower risk of de novo HBV infection in anti HBc positive (15%) compared to HBV naive recipients without prophylaxis (48%) who received liver grafts from anti HBc positive donors [26]. Similarly, Skagen et al. reported de novo HBV rates in recipients of anti HBc positive grafts as follows: 18% in previously vaccinated recipients, 14% in isolated anti HBc positive recipients, and 4% in anti HBc and anti HBs positive recipients in the absence of post LT prophylaxis [27]. However, the risk of de novo HBV infection for both HBV naive (from 48% to 12%) and HbcAb/HbsAb positive recipients of HbcAb positive grafts is reduced (from 15% to 3%) by post LT prophylaxis with HBIG and lamivudine [26]. Currently, HBIG prophylaxis is not recommended in HBsAg negative recipients regardless of the presence or absence of anti HBc and/or anti HBs [28]. When prophylaxis is used, HBV viral burden at the time of transplantation should be the determination factor of dosing and duration of HBIG [12].A meta-analysis study showed that the pooled risk of HBV transmission in HbsAb positive patients (vaccinated or resolved) receiving HbcAb positive donor grafts was similar whether or not they were on prophylactic antiviral treatment post transplantation [29]. This well highlighted the protective effect of HbsAb. These studies suggest that prior infection (HbsAb & HbcAb positive) and vaccination (HbsAb positive) have a protective role against HBV recurrence.

Post-transplant HBIG administration has become prevalent in transplant centers along with antivirals, depending on recipient's risk status to keep HBsAb titers between 100 to 500 IU/mL [30][31]. When compared, vaccination before transplant seems to be an overall better strategy than HBIG. Not just cost effective but they are also convenient and maintain sustained levels of protective HbsAb after transplant, thus decreasing the risk for transmission of HBV. Loggi et al. studied 10 patients (all were hepatitis B core antibody (HBcAb) positive who were transplanted with HBsAg positive donors and followed for 42 months. Results showed that antiviral therapy effectively controlled HBV replication with no signs of hepatitis [32]. A larger study comparing patients who underwent LT with HBsAg positive donors vs. HBsAg negative donors showed comparable results in patient and graft survivals with no difference in complications such as primary non function, acute rejection, and biliary complications [33].

In the use of HBsAg positive donors, the following criteria are recommended: normal liver function profile, donor and recipient HDV negativity, and donor pathology excluding fibrosis or significant inflammation [28]. HBsAg positive grafts should only be used if there is an option for indefinite prophylaxis with entecavir or tenofovir. The benefit of HBIG in HBsAg negative recipients of HBsAg positive grafts is unclear. Anti HBc positive grafts can be used in HDV positive recipients who are treated with antiviral plus HBIG post-transplant [34]. While the potential risk of de novo HCC is not observed in HBsAg negative recipients of anti HBc positive liver grafts who received antiviral prophylaxis post-transplant, this risk is unknown in HBsAg negative recipients who received liver from HBsAg positive donor [28][35].

Some studies have gone as far as setting cut offs for deciding management protocols for preventing donor to recipient HBV transmission. A small-scale study done in 2008 for example, involved four HbsAb positive patients receiving grafts from HbcAb positive donors. These patients received Lamivudine, and on follow up HBV infection was seen in only one patient who happened to have HbsAb titers < 10 IU/L whereas the rest of them who happened to have titers > 10 IU/L

showed no HBV infection. So, they suggested that combination treatment was not required if HbsAb titers > 10 IU/L. Another interesting study highlights the role of HBV vaccination in preventing de novo HBV infections in recipients. It suggests that certain levels of HbsAb being actively produced by the body's immune system post vaccination have a protective role and that vaccines should be given before and after transplant in all patients who are set to receive liver grafts from HbcAb positive donors. The goal of vaccination is to achieve a post operative HbsAb titer of >100 IU/L [36]. This has been shown to be protective against de novo HBV recurrence. This study further went on to say that candidates with pre operative HbsAb levels < 1000 IU/L require Lamivudine as post-transplant prophylaxis and that it can be stopped safely only when post-transplant HbsAb levels > 100 IU/L. Furthermore, patients who have pre transplant HbsAb levels > 1000 do not require prophylaxis. Notably, both cases require booster HBV vaccination after steroid withdrawal [36]. Despite having made considerable progress in this field, certain circumstances remain a contraindication for receiving HBV positive donor grafts. One such condition is the HBV/HDV, co-infected recipients. In Italy, a small-scale study was conducted on 3 HbsAg positive recipients, out of which 2 were co infected with HDV. After receiving HbsAg positive grafts, all 3 showed persistence of HbsAg despite being on HBIG, and the 2 patients who were HDV co infected showed HDV recurrence necessitating re transplantation in 1 of them [34]. Only 1 recipient who was not co infected with HDV showed promising results [34]. The reason seemed to be an HBsAg overload coming from both donor and recipient and which could not be brought under control by HBIG, leading to re activation of HDV and its undesirable outcomes. With time, improvised risk assessment tools have come up for HbsAg positive donor LT. One such tool is the HbsAg titers which are now being regularly used in the clinical scenario. The titers in donor can tell us about the risk of transmission, and in recipient, they tell us about the 'entity' of reactivation and help monitor the response towards antiviral drugs. With all the advancements and supporting data, the results look promising. To conclude, incorporating HBcAb positive grafts will further expand pool with reasonable outcomes.

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