American Society of Transplant Surgeons

Position Paper on Live Vascular Grafts

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Live vascular grafts procured from deceased donors have been an integral part of human transplantation[1,2,3] for more than 25 years. In addition, live vascular allografts have been used often for recipients of liver[4, 5], pancreas[6] and kidney[7] transplants to reconstruct damaged, diseased or surgically unsuitable donor or recipient vessels. Both fresh and preserved vessels from 3rd party donors have been used in the cited cases. Because many lives and organs have been saved in cases where no other suitable vascular reconstruction would have been possible, this routine practice should be considered potentially life saving for the transplant recipient. For many years it has been standard practice to procure vessels at the time of organ retrieval for use in reconstructing vascular inflow and outflow for solid organ transplant grafts. These live vessels are used in the original recipient or subsequently in combination of another donor's organs in another recipient.

Recently, the first case of Rabies transmission from donor to recipient was reported to have occurred via a vascular graft procured from a donor infected with rabies[8]. This incident has focused attention on the practice and storage of these vascular grafts and how this practice should be monitored and overseen. All recipients of organs and grafts from this particular donor contracted rabies. We wish to point out that the failure to identify the infection in the donor of these grafts was the root cause for the transmission of this disease to the recipients, *not* a failure of the vascular allograft storage or handling procedures at the transplant center. The ASTS is firmly committed to working to prevent inadvertent transmission of any infection from donor to recipient. However, increased regulation of vascular allograft storage and use conditions will not prevent this type of system failure. In the absence of solid data indicating that storage of these allografts *per se* poses increased risks for recipients, we urge caution in proposing new regulations of this well-established and highly successful practice.

The ASTS strongly supports improved tracking of these important vascular grafts so that donor conditions can be effectively communicated when new clinical data becomes available after the time of donor procurement procedure. This heretofore unreported event (transmission of rabies) that has driven the recent examination of these policies could potentially have been managed differently if such tracking mechanisms had been in place. However, the ASTS also wishes to emphasize that restricting the current practice of routine preservation, storage, and use of these life-saving vessels will potentially jeopardize the lives of many recipients, negatively affect utilization rates of donor organs, and adversely impact transplantation results.

The Organ Procurement and Transplantation Network (OPTN), which has responsibility for developing policies for organ donation and transplantation in the US, recently addressed this issue. At the November, 2004 OPTN Board Meeting, the following policy proposal resolution was approved:

**** RESOLVED, that Policy 5.8 "Vessel Recovery, Storage, and Transplant" as set forth below is hereby approved for public comment.**

5.0 Standardized Packaging and Transporting of Organs, Vessels, and Tissue Typing Materials
No changes to Policies 5.1-5.7.3

5.8 Vessel Recovery, Storage, and Transplant

5.8.1 The practice of vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant) should not be disrupted.

5.8.2 The sanction for vessel recovery and storage for use in a subsequent solid organ transplant from a different donor must be sustained: (for example when the vessels and the liver pancreas allograft are being transplanted from different donors with different UNOS ID numbers). The vessels cannot be used in non-transplant recipients.

5.8.3 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the Organ Procurement Organization and the Organ Procurement Transplant Network must be notified.

5.8.4 The consent forms used by the recovering Organ Procurement Organization must include language that indicates that vessels will be used for transplant.

5.8.5 If the vessels are being stored, the procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.

5.8.5.1 The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial, HTK, or others).

5.8.5.2. The vessels must be stored in a sealed container labeled with the UNOS Donor ID Number for tracking.

5.8.5.3 The vessels must be stored in a secured refrigerator at 4 degrees.

5.8.5.4 The vessels can be stored up to a maximum of 7 days.

5.8.5.5 The vessels do not have to be cultured.

5.8.5.6 There must be daily monitoring of the vessels with documented security and temperature checks

5.8.5.7 A log of stored vessels must be maintained by the transplant center at the point of storage.

The American Society of Transplant Surgeons fully supports the intent of this policy, but would like to make the following comments:

Many ASTS members indicate that they routinely store these vascular grafts for longer than seven days and have used them successfully. As indicated above, there

is a paucity of data in the literature on this subject. In one published report, live vascular allografts were used for reconstruction of failing kidney allografts after being stored for as long as 10 days with good graft results and without significant infectious risk[7]. In another recent, unpublished study, to be presented at the upcoming American Transplant Congress meeting, 59 live vascular allografts were placed in recipients within 7 days of procurement and 27 placed more than 14 days after the initial transplant. There was no difference in liver allograft survival and no evidence of increased infectious transmission[9]. The ASTS feels that current practice and the available evidence suggests that there is no data documenting what limits are reasonable for storage time for these live vascular grafts. We feel the 7-day limit proposed in this policy is too short and that item 5.8.5.4 should be modified to read:

5.8.5.4 The vessels should be stored up to a maximum of 14 days, but clinical judgment is required, as there is no data defining the safe limits of live vascular graft storage.

The policy language is somewhat confusing. The ASTS would also suggest the following changes to make it more clearly understood:

5.8.2 The vessels may be transplanted with an organ from another donor (for example, when the vessels and the liver pancreas allograft are being transplanted from different donors with different UNOS ID numbers). <u>The vessels cannot be used in non-transplant recipients.</u>

5.8.5 The procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.

5.8.5.2. The vessels must be stored in a sealed sterile container labeled with the UNOS Donor ID Number for tracking.

In relationship to 5.8.3, the ASTS suggest that the notification and tracking process be managed via UNET as an extension of the current processes to track the organs.

<u>5.8.3 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the Organ Procurement Organization and the Organ Procurement Transplant Network must be notified.</u>

The ASTS welcomes the opportunity to provide comment on this issue. Our Society represents that vast majority of transplant surgeons performing transplant procedures in the US. Our membership has the most direct experience and knowledge about the use of these vascular grafts and we are grateful to be able to supply the community with our input.

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[1] Starzl TE, Halgrimson C, Koep LJ, Weil R, Taylor P. Vascular homografts from cadaveric donors. Surg Gynecol Obstet 1979; 149: 737.

[2] Shaw BW, Iwatzuki S, Starlz TE. Alternative methods of arterialisation of the hepatic graft. Surg Gynecol Obstet 1984; 159: 490.

[3] Lillehei RC. Simmons RL. Najarian JS. Weil R. Uchida H. Ruiz JO. Kjellstrand CM. Goetz FC. Pancreatico-duodenal allotransplantation: experimental and clinical experience. Annals of Surgery. 1970; 172:405-36.

[4] Shaw BW, Iwatzuki S, Bron K, Starlz TE. Portal vein grafts in hepatic transplantation. Surg Gynecol Obstet 1985; 161: 67.

[5] Martinez JA. Rigamonti W. Rahier J. Gigi J. Lerut J. De Ville de Goyet J. Otte JB. Reding R. Preserved vascular homograft for revascularization of pediatric liver transplant: a clinical, histological, and bacteriological study. Transplantation. 1999; 68:672-7.

[6] Agnes S. Magalini SC. Serino F. Foco M. Castagneto M. Pancreatic transplantation with double arterial and venous bridge anastomosis: a technique to avoid vascular thrombosis. Transplantation Proceedings. 1987; 19(1 Pt 2):1004-7.

[7] Shames BD, OdoricoJS, D' Alessandro AM, Pirsch JD, Sollinger HW. Surgical repair of transplant renal artery stenosis with preserved cadaveric iliac artery grafts. Ann Surg, 2003; 1:116-22.

[8] Centers for Disease Control and Prevention (CDC). Investigation of rabies infections in organ donor and transplant recipients--Alabama, Arkansas, Oklahoma, and Texas, 2004. MMWR. Morbidity & Mortality Weekly Report. 2004; 53:586-9,

[9] Levy MF, Jennings LW, Sanchez EQ, et al. Deceased donor vessels as hepatic artery conduits. ATC abstract submission 252742 (used with permission)