Donor Operation and Organ Preservation

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Abstract

Orthotopic heart transplantation is an effective and definitive treatment option for advanced heart failure patients. Since the first human heart transplant, major advances have occurred in the field of heart transplantation, including new surgical strategies. There continues to be an increasing donor shortage for patients on the heart transplant waiting list. Providers need to fully understand the process of retrieving a heart from a donor and appreciate the importance of preserving the donor heart during transport. In the current chapter, the authors will review in detail a standard operative procedure during organ procurement. Important steps the organ procurement team needs to perform will be highlighted to ensure the donor heart is satisfactory for excision and transport to the recipient. Equally important, a standard method to preserve the donor heart will be described, and alternative strategies that are being studied in clinical trials will be discussed. It is imperative to maximally preserve the structure and function of the donor heart as this translates into excellent clinical

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L. Bogar, A. Stempien-Otero (eds.), *Contemporary Heart Transplantation*, Organ and Tissue Transplantation,
https://doi.org/10.1007/978-3-319-58054-8_11

outcomes for the recipient. Low morbidity and mortality rates of heart transplant recipients are dependent on the swift and precise actions of the donor procurement and recipient teams.

Keywords

Orthotopic heart transplantation · Donor operation · Organ procurement · Donor organ preservation · Bicaval technique · Biatrial technique · Ischemic time · Organ Care System · Hypothermic storage · Crystalloid preservation solutions

Introduction

In the United States, advanced heart failure is an epidemic with an estimated 500,000 patients having refractory stage D heart failure symptoms (Mancini and Naka 2015). Advanced heart failure is associated with a high mortality rate and poor quality of life. Heart transplantation has developed into an effective treatment option for these patients, with median survival of 10–15 years (Lund et al. 2013). Since the first human heart transplant, the field of heart transplantation has advanced tremendously in many aspects. Unfortunately, there continues to be an increasing donor shortage and many advanced heart failure patients are dying on the waitlist. Even today, the donor pool has not expanded rapidly enough to meet the rising demand for cardiac allografts. In this chapter, the organ procurement process, including newer donor heart preservation strategies, will be described. The operation to obtain the donor heart will be outlined in detail. At the same time, the newer surgical techniques used during the donor operation will be highlighted.

History of Heart Transplantation

The first successful human-to-human heart transplantation was performed by Christiaan Barnard in South Africa on December 3, 1967, which was 7 years after Shumway and Lower's orthotopic heart transplantation using a canine model (Allen et al. 2012). Not only did this historical event receive endless media coverage and publication in the *South African Medical Journal*, but it also laid the foundation for heart transplantation to become a feasible option for end-stage heart disease. His first heart transplant patient survived only few weeks, but 4 of his first 10 patients survived for more than 1 year. For the next 15 years, Barnard and his team continued to make significant contributions to organ transplantation, including heterotopic heart transplantation, preservation of the donor heart, and insight into the metabolic effects of brain death (Brink and Hassoulas 2009).

During that decade, several key figures attempted to make significant contributions and achieve similar success. In the 1960s and 1970s, only dedicated centers around the world continued clinical and research work in the field. Since Barnard's groundbreaking achievement, many heart centers started their own heart transplant programs but high mortality rates led to a standstill in transplant activities during that decade. Shumway and his Stanford colleagues' efforts shaped the field of heart transplantation and allowed a reemergence of the field. Shumway remained steadfast in believing good results of heart transplantation, and ultimately his group gained recognition for the most heart transplantations worldwide in the 1970s (Schmitto et al. 2008).

By the mid-1960s, many physicians in the field of heart transplantation gathered considerable knowledge and learned from the previous work from pioneers such as Demikhov (1965), Carrel and Guthrie (Cooper 1968), and Stansel and Terino (1965). Physicians adopted the basic principles of heterotopic heart transplantation, cardio-pulmonary bypass, hypothermia, and preservation of the donor heart. Physicians also expanded on the concept of brain death and when brain death laws were enacted in 1981 the field of transplantation grew due to the better acceptance of organ donation in brain death. Although Christiaan Barnard's first successful human-to-

human heart transplantation was a remarkable achievement and laid the foundation for the field, earlier experiences from pioneers should be recognized. Nevertheless, Christiaan Barnard has been credited for the first successful human-to-human heart transplantation, and his work still echoes today, allowing heart transplantation to a viable treatment for advanced heart failure patients.

Epidemiology

The annual data report of organ donation and transplant by UNOS (United Network for Organ Sharing)/OPTN (Organ Procurement and Transplantation Network), which was updated March 2016, reports on the average 2500–3000 new patients are listed for heart transplant each year, and approximately 4000 patients total are on the heart transplant waiting list. There is equal number of patients added to the heart transplant waiting list as the number of patients removed from the list. The majority of the adult patients on the heart transplant waiting list are 50–64 years-old, Caucasian, blood type O, and suffer from advanced heart failure due to coronary artery disease or a specific type of cardiomyopathy. On the average, they spend 1–2 years on the waiting list, with a majority of the patients on the list less than 1 year. Most patients who have median wait times of 10 months are either status 1 or have a VAD (ventricular assist device). Approximately 2% per year are listed for combined heart-lung transplant.

The total number of heart transplants in the Unites States has been steadily above 2000 every year since 2000, and 4000 worldwide. Approximately, 1.7–2% per year receives a combined heart-lung transplant, and 3–4% per year receive their second heart transplant. Most of the heart donors are very young (15–34 year-old) white non-Hispanic males. The most common causes of death among the deceased heart donors are head trauma, anoxia, or a cerebrovascular accident ("Annual Report" 2016).

Donor Operation

When Christiaan Barnard in South Africa performed the first orthotopic heart transplant in 1967 (Allen et al. 2012), the technique he employed utilized a biatrial anastomotic technique. This is the technique developed by Norman Shumway and Richard Lower (Lower and Shumway 1960). This elegant and efficient method was successfully used for over 20 years worldwide and avoided the technical difficulty of separate caval and pulmonary vein anastomoses. This approach entails a simple anastomosis of both atria at midlevel and also of the pulmonary artery and aorta above the valves. This method retained the left and right atria of both the donor and the recipient (Lower et al. 1961). It was clear this was a quick and effective strategy that avoided potential complications of venous thrombosis and stenosis (Cass and Brock 1959; Barnard 1968). Unfortunately, long suture lines on the right atria also led to sinus node dysfunction and tachyarrhythmias. Barnard et al. recognized this issue and modified the surgical strategy. Instead of a posterior incision in the right atrium from the inferior vena cava (IVC) to the superior vena cava (SVC), which would increase the risk of sinus node dysfunction, Barnard and his Stanford colleagues would avoid the sinus node area. They would ligate the donor SVC 1–2 cm above its entrance into the right atrium and open the right atrium by an incision that extended from the IVC up the lateral aspect of the atrium into the right atrial appendage (Barnard 1968) (Fig. 1a). However, having large atrial cavities resulted in the loss of atrial geometry and anatomy, which led to several postoperative complications including mitral and tricuspid regurgitation, atrial septal aneurysms, and atrial thrombus formation.

Due to these postoperative complications, alternative anastomotic techniques were developed over the past several decades in an attempt to maintain the normal shape of the atria. One such method was the bicaval technique, which was widely and rapidly adopted and has become the most frequently used technique at present (Sarsam et al. 1993). Webb et al. are recognized as the first to

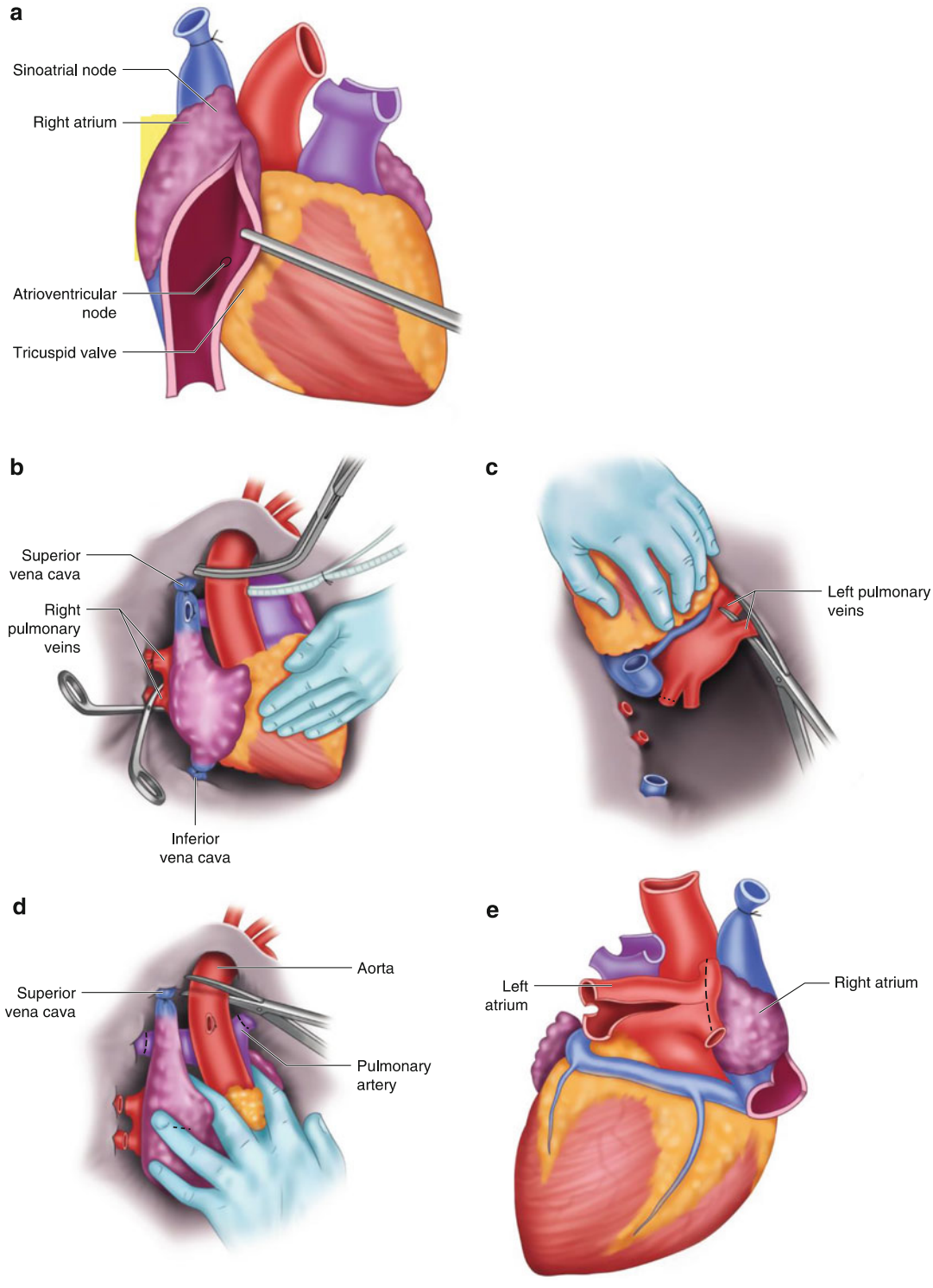

Fig. 1 (continued)

successfully perform the bicaval technique in dogs in 1959. They established an 8-anastomosis model, including individually connecting each of the pulmonary veins (Webb et al. 1959). Little over 3 decades later, a 6-anastomosis model was developed, which reduced the pulmonary vein connection to a left and a right pulmonary vein major orifice. The recipient's residual tissue is prepared with a left and right pulmonary vein cuff, which was anastomosed to the 2 orifices (Yacoub and Banner 1989; Dreyfus et al. 1991). In 1990s, this was first described and implemented. By the 2005, the bicaval surgical method was performed more than the biatrial strategy. However, in a large series examining the UNOS database, the results showed no difference in survival between the standard biatrial and the bicaval techniques (Weiss et al. 2008). With the bicaval strategy, the normal atrial morphology is retained which has the theoretical advantages of preserved atrioventricular valve competence, atrial contractility, and sinus node function. From a technical perspective, although there is an extra anastomosis to be performed, the bicaval technique is a simple and efficient surgical method without resulting in increased ischemic time. When compared to the biatrial technique, several studies have shown many advantages of the bicaval technique. These include lower right atrial pressures, lower incidence of tricuspid valve incompetence, and reduction in atrial arrhythmias as well as improvements in hemodynamics, cardiac chamber dimensions, cardiac output, right ventricular function, and exercise capacity. Today, the bicaval technique (5-anastomosis model) is the most common method in orthotopic heart transplantation and is associated with better hemodynamic outcomes than the standard biatrial method (Milano et al. 2000). This method has gained worldwide acceptance as the procedure of choice for OHT.

Organ Procurement

Upon arriving at the donor center, all reports are reviewed. These include donor/recipient blood group and compatibility, brain death notes, and reports of cardiac catheterization (if performed), echocardiograms, chest x-rays, and electrocardiograms. The images of the echocardiograms, chest x-rays, and cardiac catheterization should also be reviewed if available. Several communities will consent to organ donation with the exception of the heart. Hence, consent should also be reviewed with particular attention to cardiac donation. Finally, donor hemodynamics and inotropes/vasopressor requirements are also reviewed. If there are any concerns, a Swan-Ganz catheter and/or a transesophageal echocardiogram (TEE) should be performed. Any unanticipated cardiac abnormalities are discussed immediately with the recipient implant team.

In an effort to standardize thoracic organ procurement and preservation, Pasque describes an efficient and uncomplicated method (Pasque 2010). A standard midline incision is performed. This is usually connected to the abdominal incision if abdominal solid organs are also being procured. Bone wax is used and the chest is spread with a sternal retractor. The pleura are usually opened bilaterally if the lungs are also being procured. If only the heart is being procured from the thoracic cavity, then the right pleura should only be opened for access to the right pulmonary veins. A standard pericardial well is then made. Three pericardial sutures (large silk sutures) are placed on each side and snapped to a Kelly clamp. This

Fig. 1 Steps of isolated heart procurement. (**a**) In the atrial anastomosis technique, an incision is performed from the orifice of the IVC towards the right atrial appendage, avoiding the sinus node. (**b**) Cardioplegia has already been applied, the heart is arrested, and an aortic crossclamp has been applied. The SVC (superior vena cava) and IVC (inferior vena cava) are transected. (**c**) The heart is retracted towards the head to complete the transection of the PVs (pulmonary veins) at the pericardial edge. (**d**) With gentle retraction of the heart caudally, the pulmonary arteries are divided at the pericardial reflection and the aorta is transected (if possible after the left common carotid artery). (**e**) After the PVs are divided, an atrial cuff is formed with a left atrial incision in preparation for anastomosis during implantation (Blitz 2017)

will make it easier to gain access to the pleural spaces later in the procedure. At this stage, the heart and great vessels are inspected for any congenital, traumatic, or unanticipated abnormalities. The heart is examined for any palpable thrills and ventricular dysfunction. It is important to manually palpate the coronary arteries to assess for plaque or calcification. At this juncture, the expected crossclamp time should be ascertained and relayed back to the implantation team. Very minimal dissection is now performed so as not to cause much hemodynamic embarrassment until the patient is almost ready for crossclamp. The SVC is encircled at its origin from the innominate vein and the pericardial reflection is dissected off the origin of the arch vessels. The AP window is developed enough for a cross clamp to be placed. Once the patient is fully heparinized (30,000 units of heparin), an antegrade cardioplegia cannula is inserted in the mid ascending aorta and held in place with a Rommel tourniquet using a 5–0 polypropylene suture. The IVC is then encircled for ease of division at a later time so as not to injure the right inferior pulmonary vein. Waterson's groove can now be developed if the lungs are also to be procured. It is important to ensure that all organ procurement teams are ready prior to cross clamping. At that time, the SVC is ligated (after any upper body central venous lines are removed). A generous cut is made on the tip of the left atrial appendage to vent the left side of the heart. The incision needs to be big enough so as not to be obstructed by topical slush, but should not encroach upon the circumflex coronary artery. If the lungs are not being procured, the left atria can be vented by making a large cut on the pleural side of the right or left pulmonary veins. Finally the IVC is partially divided at a position suitable to both the liver and cardiac teams. These maneuvers will ensure optimization of left ventricular decompression and avoid distention upon crossclamping of the aorta. Once the aorta is crossclamped, the cardiac preservation fluid is infused at approximately 80 mmHg. At least 1 L of cold crystalloid cardioplegia solution is infused. There should be persistent aortic distension with rapid cessation of the cardiac activity without any ventricular distention. Topical cooling can now be used in the form of ice slush. If the heart feels full or hard, it is imperative to quickly assess the cause. The cross clamp may need to be removed and gentle pressure applied to empty the left ventricle prior to replacing the cross clamp. If the problem persists, it may result in a non-functioning or damaged graft. This is likely the most important element in the heart procurement process. Also, the cardioplegia should continue to be given until all the pulmoplegia is completed so as to avoid inadvertent pulmoplegia entering the coronary arteries. Next, the IVC and SVC are transected (Fig. 1b). The azygous vein is transected freeing the entire SVC. The azygous vein can be used as a guide to prevent twisting of the eventual SVC anastomosis. If the lungs are not being procured, then the pulmonary veins and arteries can be divided at the pericardial reflection (Fig. 1c). Otherwise, the atrial incision is started at Waterson's groove. Further extension of the left atrial incision is carried out towards the IVC and then parallel to the AV groove towards the left atrial appendage to the left. The right pulmonary veins can now be visualized and the left atrial incision is carried up the right keeping at least a 1 cm cuff for subsequent cardiac implantation. The rest of the atrial incision is completed from inside the left atrium, after the aorta and main pulmonary artery are divided. The left atrial appendage should be kept with the donor heart as a landmark for subsequent left atrial anastomosis. The innominate and left common carotid arteries are divided. If possible, the aortic arch is transected just beyond the left common carotid artery avoiding any injury to the pulmonary artery at the ligamentum arteriosum. However, division of the aorta before the aortic arch is adequate (Fig. 1d, e). The main pulmonary artery is transected at the level of the pulmoplegia cannulation site (distal main PA). This is only required if the lungs are also being procured. Otherwise, the pulmonary arteries would already have been divided at the level of the pericardium.

The heart is removed from the field and inspected for any previous undetected abnormalities or surgical damage. The atrial septum is inspected for a patent foramen ovale, and, if

present, will be closed by the donor surgeon or the implant surgeon. The aortic, mitral and tricuspid valves are inspected for thickening or adherent masses. The donor heart is now submerged in a plastic bag containing cold preservation solution without ice. This bag is sealed and placed within another bag containing cold fluid with ice. This second bag is sealed and now placed in a sterile plastic transportation canister, which is tagged with the donor's UNOS number and blood type and finally placed in an ice-filled cooler for transportation.

Donor Organ Preservation

It is imperative to maximally preserve the structure and function of the donor heart during transport. According to the International Society of Heart and Lung Transplant (ISHLT) registry, the 30-day mortality after heart transplantation is 8%. The leading cause of death 30 days after heart transplantation is primary graft failure (PGF). The 2 main risk factors for PGF are donor age and the length of ischemic time of the donor heart (Stehlik et al. 2012). Ischemic time for the donor heart starts with aortic cross clamp in the donor and ends with the removal of the aortic cross clamp in the recipient. A 3-h ischemic time is currently an acceptable time frame for graft preservation (Russo et al. 2007). The ISHLT registry has shown that the presence of PGF leads to a subsequent increase in 1-year and 5-year mortality rates; these increase once ischemic time surpasses 3 h. In the United States, the median ischemic graft time is 197 min (Fischer and Glas 2013). The length of the ischemic time is influenced by several factors, including experience of the procurement team, distance between the donor and recipient hospital, and experience of the receiving heart transplant team.

The Organ Care System (TransMedics, Andover, Massachusetts) is one strategy used to reduce the ischemic time. Organ Care System (OCS) is a transportable commercial system that allows a living organ transplant to be preserved during transport in a portable warm blood perfusion system. The Organ Care System consists of a miniature pulsatile pump with an inline heater and oxygenator. A solution that contains crystalloid combined with oxygenated warm donor blood allows the donor heart to beat ex vivo in a warm functioning state (Yeter et al. 2011; Ghodsizad et al. 2012). This is the first commercial device to transport donor hearts in a normothermic perfused state. The current OCS perfusion module maintains the heart in a state that was previously assessed within the donor and allows transportation to be feasible in a controlled state. During transport, the hearts are continuously assessed with aortic pressures, coronary blood flow, and metabolic profiles measurements. Two trials, 1 in Europe and 1 in the United States, evaluated the OCS in heart transplantation. The US-based Proceed II trial studied the safety and efficacy of OCS to the standard of care of cold storage and transport of the donor heart. In the Proceed II trial, the 30-day patient and graft survival were increased in the OCS arm versus the cold storage arm (Messer et al. 2015). Animal data has also shown normothermic blood perfusion to be superior to cold storage in preserving donor hearts in dogs (Rapse et al. 2010). For over four decades, cold storage has been the norm for donor preservation because of its simple and inexpensive technique. However, normothermic donor heart perfusion has expanded the number of potential donors and may improve 30-day outcomes after heart transplantation. OCS has the potential to retrieve donors from far geographic regions and extend beyond boundaries otherwise not possible. A donor heart can successfully be transplanted from far regions because OCS has the ability to maintain organ perfusion and minimize ischemic time. Also, OCS avoids high-speed journeys to the recipient hospital because there is no urgency related to ischemic time. OCS also offers flexibility to the receiving transplant team as it gives them time to assess the quality of the donor heart and to carefully prepare the recipient for the implant; this is particularly helpful with redo sternotomy cases especially those with LVADs in place. While OCS provides safety advantages and improved mortality outcomes due to reduced ischemic times, OCS also has the potential to capitalize on marginal hearts. Marginal hearts are those

hearts that are less desirable; these hearts may come from donors that are older, have some left ventricular hypertrophy or a lower ejection fraction. Using the standard cold preservation technique, marginal hearts would traditionally not be utilized for heart transplantation because they would have poor function and associated worse outcomes (Kilic et al. 2014). Normothermic donor heart perfusion with OCS offers many clinical advantages and opportunities given the current research.

Most transplant centers still prefer hypothermic storage with a single flush of a cardioplegic or preservative solution. There are many crystalloid solutions with a wide range of different compositions. Solutions are classified as intracellular or extracellular depending on the potassium and sodium concentrations (Conte and Baumgartner 2000). Intracellular solutions are characterized by high concentrations of potassium and low concentrations of sodium in order to reduce hypothermia-induced cellular edema. Examples of this composition include University of Wisconsin, Euro-Collins, intracellular Stanford solutions, and Bretschneider (Europe). University of Wisconsin is one of the most common solutions being used. Extracellular solutions are composed of low to moderate potassium and high sodium concentrations to avoid cellular damage. Examples include Hopkins, Celsior, Krebs, and St. Thomas Hospital solutions. Many studies have compared the different type of intracellular and extracellular cardioplegic solutions with variable results (Wildhirt et al. 2000; Garlicki 2003). There is no ideal solution despite on-going debates as to which is the best preservative solution.

In clinical trials, comparable levels of myocardial protection from ischemic injury were provided by these various crystalloid preservation solutions. There has been a focus on optimizing the composition of existing heart preservation solutions and creating new solutions. Anti-ischemic agents have been added to standard heart preservation solutions (Minasian et al. 2015). For example, glyceryl trinitrate, erythropoietin, and zoniporide have been added as single or combined supplements to Celsior solution, which activate the intracellular kinases and mediate ischemic pre-conditioning and post-conditioning (Iyer et al. 2014). The concept of cardio-protection by ischemic conditioning has been extensively demonstrated where recurrent episodes of short ischemic preconditioning protect the heart from a subsequent long period of ischemic insult (Murry et al. 1986). Additional advancements in the standard solutions include increasing the buffer capacity and adding colloid parts to the solutions. A balanced acid-base solution is crucial to maintain glycolytic ATP production during ongoing ischemia. Another important aspect is increasing colloids, such as high molecular weight dextran, gelatine, and hydroxyethyl starch (HES) to prevent intracellular edema and protect endothelial function (Zausig et al. 2013). Animal models have shown promise, but studies need to be investigated into plasma-based heart preservation solutions in marginal hearts (Jacob et al. 2009). Several new heart preservation solutions have been developed in animal models, including Somah, CRMB, Krebs-Henseleit buffer-based (KHB), and Custodiol-N. These new solutions have shown to be more effective than standard solutions. However, numerous pre-clinical studies need to be performed before being tested in clinical trials.

Other strategies of donor heart preservation include sub-zero temperature and oxygen persufflation. Prior reports have described decreased myocardial oxygen consumption during cold storage of the donor heart at +4 °C, but attempts are being made to achieve sub-zero temperatures at −3.0 °C. In order to prevent irreversible cell damage due to sub-zero temperatures, the donor hearts are submersed in anti-freeze proteins, which have cryoprotective properties. Kato et al. have shown submerging rat hearts in UW preservation solutions at sub-zero temperatures resulted in improved post-ischemic LV function, increased ATP levels, and decreased tissue edema (Kato et al. 2012). Oxygen persufflation, or perfusion of the coronary vascular bed with humidified gaseous oxygen, is another experimental technique dating back to the early 1960s (Suszynski et al. 2013). Oxygen persufflation was designed to reduce myocardial hypoxia during cold storage. This strategy makes myocardial perfusion possible to the heart even during reduced cold-induced

metabolic states. Animal models have shown antegrade persufflation resulted in better functional recovery of the LV function after orthotopic heart transplantation than the conventional cold storage method (Kuhn-Regnier et al. 2000). Thus, these 2 experimental strategies may be interesting options for donor heart preservation, and will need further clinical investigation.

At the center of donor heart preservation is minimizing graft dysfunction caused by ischemic-reperfusion injury, which occurs during the ex vivo transport to the receiving hospital. Currently, the universal method of transport involves cold storage in a crystalloid preservation solution. Although improvements have been made to the current strategy, ischemic injury continues to occur in a certain proportion of cardiac grafts due to increased transport times and poor preservation techniques. The growing shortage of donor hearts, the existence of "marginal donors," and the concern for graft dysfunction has stimulated the creation of new techniques of heart preservation, which have shown some initial promise.

Conclusion

Orthotopic heart transplantation is a definitive treatment for advanced heart failure patients. The field of heart transplantation has evolved immensely, especially with newer surgical strategies. With the advent of the bicaval technique, post-operative complication rates have diminished in comparison to the biatrial technique. Once a donor heart has been identified, the organ procurement team has to be precise and timely during the organ retrieval process. Even before the surgeon makes the first incision, the team must critically review the donor's clinical status and confirm that the organ is suitable for the recipient. It is only then the surgeon proceeds forward with the donor operation. It is understood there are variations in the proposed surgical procedure that was reviewed. Equally important, the team must maximally preserve the structure and function of the donor heart during transport. Currently, the universal method of transport involves cold storage in a crystalloid preservation solution. Alternative preservation examples include the Organ Care System, a portable warm blood perfusion system, and sub-zero temperature solutions with anti-freeze proteins. Many other preservation strategies are being tested in clinical trials. The organ procurement cascade ends when the donor heart has been successfully implanted into the recipient. The clinical outcomes of heart transplant recipients are dependent on the swift and precise actions of the donor procurement and recipient teams.

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