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Concurrent Left Ventricular Assist Device (LVAD) Implantation and Percutaneous Temporary RVAD Support via CardiacAssist Protek-Duo TandemHeart to Preempt Right Heart Failure

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Right ventricular failure (RVF) is an unfortunate complication that continues to limit outcomes following durable left ventricular assist device (LVAD) implantation. Despite several 'RVF risk scores' having been proposed, pre-operative prediction of post-LVAD RVF remains a guesstimate at best. Current strategies for institution of temporary RVAD support are invasive, necessitate additional re-thoracotomy, restrict postoperative mobilization, and/or entail prolonged retention of prosthetic material *in-situ*. The authors propose a novel surgical strategy comprising simultaneous implantation of a permanent LVAD and percutaneous TandemHeart® plus ProtekDuo® to provide temporary RVAD support and preempt RVF in patients with impaired RV function.

MeSH Keywords: **Cardiac Surgical Procedures • Heart Failure • Life Support Systems**

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Background

Ventricular assist device (VAD) therapy is a well-established pathway in the surgical treatment of severe heart failure. Nevertheless, utilization of left VAD (LVAD) therapy by far outnumbers right VAD (RVAD) or biventricular assist devices (BiVAD) in contemporary clinical practice [1]. Current options for long-term biventricular support include the Berlin Heart Excor® system (Berlin Heart GmbH, Berlin Germany) [2,3] and total artificial heart (TAH) [4], while the concomitant use of two 3rd generation VAD as BiVAD remains mostly experimental at present [5]. Since postoperative right ventricular failure (RVF) often determines the difference between successful or adverse outcomes following LVAD therapy, anticipating and tackling RV dysfunction assumes even greater importance in the current era as surgeons continue to push the envelope with LVAD implantation in their attempts to help increasingly sicker patients. We describe our technique of simultaneous implantation of permanent LVAD and percutaneous TandemHeart® plus ProtekDuo® cannula to provide temporary RVAD support and preempt RVF in patients with impaired RV function.

Right Heart Failure Limits Outcomes Following LVAD therapy

While LVAD therapy currently entails highly standardized surgical techniques, immediate right ventricular failure (RVF) is a well-documented life-threatening complication following LVAD implantation [6,7]. We have previously addressed the issue of preoperative determinants of the need for RVAD therapy following LVAD implantation [8]. Others have also presented comprehensive reviews of post-LVAD RVF [9]. In general, RVF may occur intraoperatively (acute RVF) or within days after surgery (subacute RVF), and is associated with a significant increase of ICU stay, morbidity and mortality. However, if RVF cannot be remedied by conservative management with inotropic support, nitric oxide inhalation and fluid restriction, urgent temporary mechanical right ventricular support may be indicated.

Pathophysiologically, post-LVAD RVF is mainly triggered by maladaptation of RV preload and afterload, with contributory perioperative factors such as morbidity of surgery, cardiopulmonary bypass (CPB) and suboptimal fluid balance management. Whereas LVAD implantation immediately reduces RV afterload, cardiac output following LVAD implantation reflects biomechanical output and may confound assessment of native right heart function to guide the need for RVAD support. Nevertheless, subsequent (catch-up) initiation of RVAD support may not be as efficacious as RVAD therapy instituted simultaneously at the time of LVAD implantation, especially in patients with pre-existing RV impairment.

Current techniques of implantation of a temporary RVAD involve drainage of the right atrium (by insertion of either right atrial or femoral venous cannulae) to an extracorporeal centrifugal pump (with/without oxygenator) that pumps the blood into the pulmonary artery trunk, thereby bypassing the right ventricle. Although this approach allows for full right heart support and subsequent weaning, it is often associated with greater surgical invasiveness, need for additional re-thoracotomy for decannulation, restricted postoperative mobilization and/or prolonged retention of prosthetic material *in-situ* (in case of a prosthetic graft anastomosed to the pulmonary artery and tunnelled intercostally) [10,11].

TandemHeart® Plus ProtekDuo® Dual-Lumen Cannula Allows Minimally Invasive Full-Flow Right Heart Support

In an effort to overcome the aforementioned limitations of conventional temporary RVAD therapy, we sought to provide biventricular support with the simultaneous implantation of a permanent LVAD and a TandemHeart® plus ProtekDuo® cannula (CardiacAssist Inc., Pittsburgh, PA 15238, USA) temporary RVAD.

TandemHeart® by CardiacAssist® is an extracorporeal hydrodynamic continuous flow centrifugal pump for temporary circulatory support that can provide up to 8 L/min of flow. Strategies for TandemHeart® support may be either veno-venous, with separate cannulation of jugular and femoral veins, or veno-arterial, via peripheral venous and arterial cannulation (15 or 17 Fr). An oxygenator can be incorporated into the circuit if concurrent pulmonary support is indicated. Additionally, a 21 Fr. cannula can be deployed trans-septally to vent the left heart if needed, to prevent LV distension and back-pressure pulmonary dysfunction.

The recently introduced ProtekDuo® cannula, in combination with the TandemHeart® pump, offers the advantage of minimal invasive percutaneous full right heart support. The ProtekDuo® cannula is a flexible, dual-lumen and partially wire-reinforced cannula providing drainage of venous blood through the outer 29 Fr. lumen from the right atrium and output through the tip of the inner 16 Fr. cannula into the pulmonary artery, with optional pulmonary support by adding an oxygenator into the circuit (Figure 1). Khalpey et al. recently described minimally invasive temporary biventricular full-flow support using two ProtekDuo® cannulae, with left side support provided by a modified shortened ProtekDuo® cannula placed transapically and passed across the aortic valve, draining the LV and ejecting into the ascending aorta [12]. The ProtekDuo® cannula and TandemHeart® pump are approved for clinical use for a period of up to 30 days by the European Medicines Agency (EMA) and up to 6 days by the U.S. Food and Drug Administration (FDA).

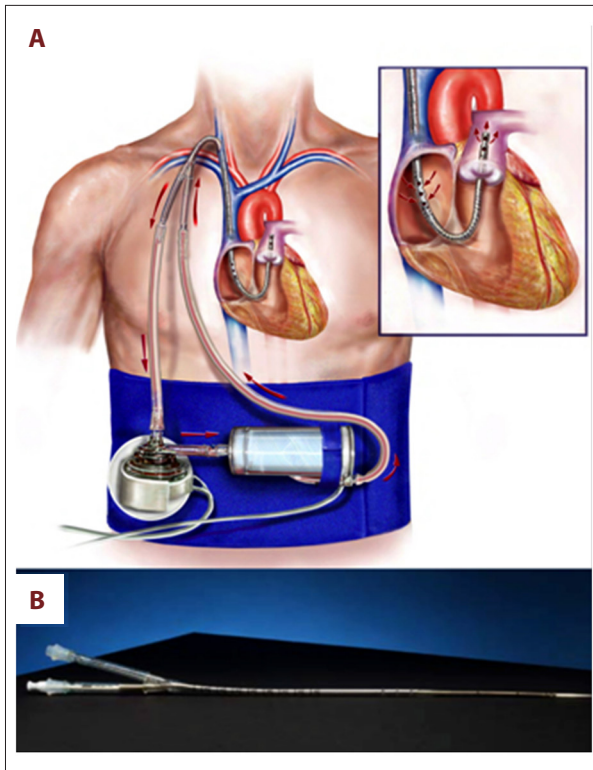


Figure 1. (A) Schematic illustration of the ProtekDuo[®] cannula *in-situ* with pump attached to the body vest. An oxygenator can be interposed to maintain full lung support; (B) Picture of the coaxial dual-lumen wire-reinforced 29 Fr. ProtekDuo[®] cannula. (Both pictures reproduced with kind permission of CardiacAssist Inc., Pittsburgh, PA).

Surgical Technique of Simultaneous Permanent LVAD and Temporary RVAD Support Using the ProtekDuo[®] Cannula

Our strategy of concurrent percutaneous implantation of a full support RVAD is independent of the surgical approach utilized for LVAD implantation, either via median sternotomy or minimally invasive via a limited thoracotomy, with or without CPB. After LVAD is placed and outflow cannula anastomosed to the ascending aorta, the ProtekDuo[®] cannula is inserted percutaneously through the right internal jugular vein (Figure 1A). The cannula is placed in Seldinger technique over a Swan-Ganz-catheter into the pulmonary trunk. Correct placement is confirmed by intraoperative transesophageal echocardiography (TOE) and fluoroscopy, and both lumens are connected to the pump. RVAD support is then initiated and progressively increased (as needed) to a maximum flow of 3.8 L/min with concurrent weaning of CPB flow (if applicable) and increase of LVAD support, with inotropic support and/or inhaled nitric oxide (iNO) if indicated. If the LVAD implantation is carried out on CPB, it is advisable to insert the guidewire before establishing full CPB flows, as guidewire insertion may be rendered difficult once the right heart is emptied by CPB. Intraoperative TOE can help to optimize right and left sided flows. We utilize complete post-procedure heparin reversal to secure hemostasis. Beside TOE (Figure 2A), correct placement of the cannula can also be confirmed on the postoperative chest X-ray showing LVAD and ProtekDuo[®] cannula in place (Figure 2B). Postoperative anticoagulation protocols for TandemHeart support are similar to those of modern 3rd generation permanent LVADs, with a target activated partial

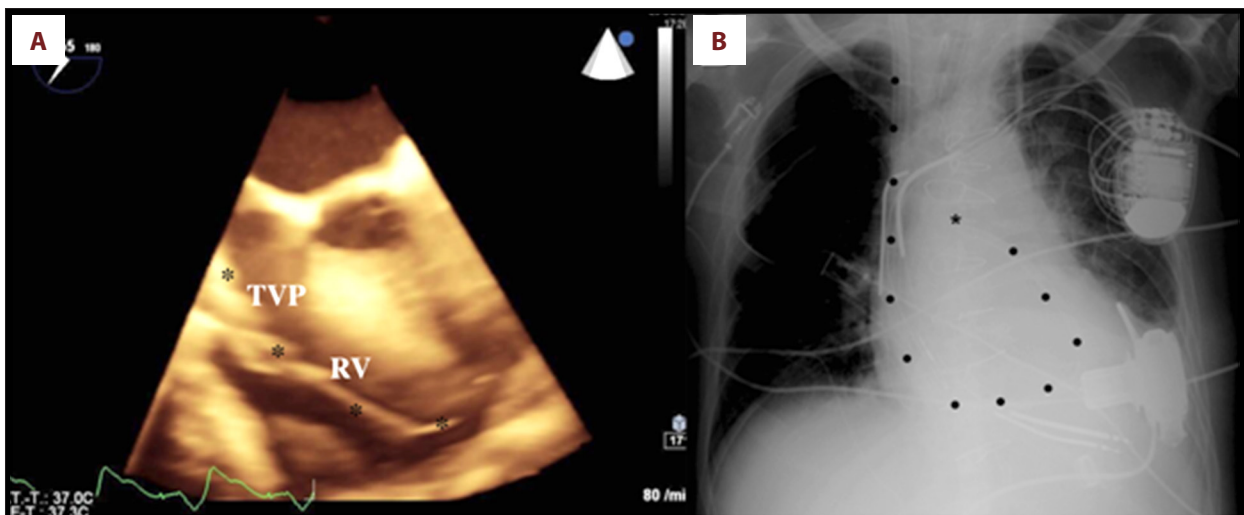


Figure 2. (A) Intraoperative three-dimensional echocardiographic picture of the ProtekDuo[®] cannula *in-situ*. Course of cannula passing the tricuspid valve plane (TVP) into the right ventricle (RV) to enter the pulmonary trunk. (B) Early postoperative chest X-ray illustrating continuous apex LVAD in place as well as percutaneous temporary RVAD cannula (for higher visibility, course of cannula is indicated with black dots, asterisk is indicating the tip of the inner cannula in the pulmonary artery).

thromboplastin time (aPTT) range 60–80s and activated clotting time (ACT) range 180–220 s. Of note, due to the design of the TandemHeart® pump housing, continuous flushing with heparinized saline is mandatory.

Temporary RVAD Support Allows Full Mobilization and Controlled Weaning

Full biventricular support prevents RVF and may therefore be associated with fewer postoperative complications. Whereas patients in RVF often require an extended period of ventilation, temporary RVAD support may allow for early ventilator weaning and extubation. However, with conventional RVAD strategies, postoperative mobilization is limited and/or associated with increased risk of vessel damage and life-threatening accidental decannulation. Using the trans-catheter temporary RVAD support with the ProtekDuo® cannula, patients can be fully and safely mobilized with the cannula, pump (and oxygenator, if used) securely attached to a purpose-specific thoracic vest.

For weaning, the TandemHeart® centrifugal pump allows a progressive decrease of support down to a minimum flow of about 1.8 L/min. Following successful gradual weaning of RVAD support, the cannula can be removed at the bedside without leaving behind any prosthetic material *in-situ* and without the need to return to Theatres for decannulation.

Discussion

A growing number of candidates for LVAD therapy present with limited RV function, warranting consideration of concomitant RVAD support. Although BiVAD support is an established treatment modality for biventricular failure, it is associated with worse outcomes as compared to LVAD therapy [13].

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Moreover, conventional BiVAD support is mainly utilized as part of a bridge-to-transplant strategy, with infrequent use in patients accepted for destination therapy.

Whereas LVAD therapy alone (without RVAD) has consistently been associated with superior outcomes, secondary initiation of RVAD support for post-LVAD RVF is associated with increased morbidity and mortality [6,7]. On the other hand, planned temporary RVAD support has shown to improve outcomes after LVAD implantation in patients with RVF, but not in the absence of established RVF[14]. Thus, the argument for or against temporary RVAD support concurrent with LVAD implantation is seldom straightforward, and pre-existing RV dysfunction may influence the threshold for LVAD implantation by surgeons in accordance with their individual/institutional experience and/or capabilities. The same holds true for secondary (post-LVAD) RVAD implantation, which may be further encumbered by the additional need for a re-sternotomy. The percutaneous method of temporary RVAD support proposed herein encompasses the advantages of being minimally invasive and offering full-flow hemodynamic and oxygenation support if needed, without encumbering subsequent patient mobilization and without the need for return to Theatres for surgical explantation.

Conclusions

In summary, we believe that a percutaneous temporary RVAD employed with a single-stage implantation technique as described herein allows for a low threshold to simultaneously support and protect the “borderline” RV at time of LVAD implantation. A preemptive, minimally invasive, temporary RVAD implantation should be considered in patients with likely RV dysfunction, rather than as an afterthought or last resort following post-LVAD RVF.

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