Percutaneous Superior Vena Cava Drainage During Minimally Invasive Mitral Valve Surgery: A Randomized, Crossover Study

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Objective: **Minimally invasive techniques commonly are applied to mitral valve surgery; however, there has been little research investigating the optimal methods of cardiopulmonary bypass for the right minithoracotomy approach. Controversy exists as to whether a percutaneous superior vena cava drainage cannula (PSVC) is necessary during these operations. The authors, therefore, sought to determine the effect of using a percutaneous superior vena cava catheter on brain near-infrared spectroscopy, blood lactate levels, hemodynamics and surgical parameters.**

Design: **Randomized, blinded, crossover trial.**

Setting: **Tertiary care university hospital.**

Participants: **Patients undergoing minimally invasive mitral valve surgery via a right minithoracotomy.**

Interventions: **Twenty minutes of either clamped or unclamped percutaneous superior vena cava neck catheter drainage, during mitral valve repair.**

Measurement and Main Results: **For the primary outcome of brain near-infrared spectroscopy, there were no differences between the two groups (percutaneous superior vena cava clamped 55.0% ± 11.6% versus unclamped 56.1% ± 10.2%) ($p = 0.283$). For the secondary outcomes pH (clamped 7.35 ± 0.05 versus unclamped 7.37 ± 0.05 $p = 0.015$), surgical score (clamped 1.96 ± 1.14 versus unclamped 1.22 ± 0.51 $p = 0.002$) and CVP (clamped 11.6 mmHg ± 4.8 mmHg versus unclamped 6.1 mmHg ± 6.1 mmHg $p < 0.001$) were significantly different.**

Conclusions: **The use of a percutaneous superior vena cava drainage improved surgical visualization and lowered CVP, but had no effect on brain near infrared spectroscopy during minimally invasive mitral valve surgery. (ClinicalTrials.gov Identifier: NCT01166841)**

KEY WORDS: minimally invasive surgery, cardiac surgery, mitral valve surgery, superior vena cava drainage, cardiopulmonary bypass, transesophageal echocardiography, anesthesia

THE RIGHT ANTEROLATERAL minithoracotomy approach to the mitral valve was first described in 1987 as an alternative approach for reoperative surgery.[1] Minimally invasive valve surgery was further refined with smaller incisions and endoscopic visualization in the mid-1990s[2–5] and has since evolved to become a commonly performed approach for repair of the mitral valve.[6–8] Its main advantages are endoscopically-enhanced visualization of the mitral valve, less blood loss, and faster recovery while providing a superior cosmetic result following surgery. Its greatest benefit may lie in reoperative procedures in which it avoids the risks of repeat sternotomy.

Various arterial cannulation strategies have been employed in minimally invasive mitral valve surgery, with some centers utilizing direct femoral arterial cannulation, some using Dacron side-grafts to the axillary artery and others central aortic cannulation. Venous cannulation has evolved, from central direct dual cannulation of the inferior vena cava (IVC) and superior vena cava (SVC), to the more common method of femoral venous cannulation with a long multistage cannula; however, the venous cannula's length and relatively small caliber may provide inadequate venous drainage, resulting in only partial cardiac emptying and suboptimal surgical visualization. One solution is the addition of a percutaneous superior vena cava (PSVC) cannula, which assists venous drainage, particularly when left atrial retraction may partially obstruct normal SVC drainage. This also may have a beneficial effect on brain perfusion by improving jugular venous drainage during these long operations; however, there remains uncertainty as to the necessity of a PSVC cannula because it requires additional time and skill without clear identified benefit. Therefore, many experienced centers opt not to routinely place PSVC cannulae.[7]

There currently are no randomized trials comparing cardiopulmonary bypass (CPB) with and without a PSVC cannula during minimally invasive mitral valve repair with which to accurately assess the benefits and risks of this approach. The authors therefore, sought to determine the effects of the PSVC cannula on brain perfusion using the surrogate measure of near-infrared spectroscopy. They also sought to assess secondary outcomes including: Hemodynamic indices, perfusion parameters and surgical visualization, estimated on a four-point Likert scale.

METHODS

The study was designed as a blinded, randomized, crossover trial. After internal review board approval and informed written consent, patients were randomized to undergo a 20-minute period of PSVC cannula cross-clamping (to act as a surrogate for the cannula not being placed) or a 20-minute period of unclamping (baseline measurements were made while the cannula was unclamped) during the 40-minute study period. The intervention began after the trans-thoracic aortic cross-clamp was applied and the left atrium was opened to expose the mitral valve. Each patient then was switched to the second intervention after 20 minutes. Both the surgeon and perfusionist were blinded to both the intervention and brain near-infrared saturation (BNIR). The anesthesiologist performed the intervention with the clamp either applied to the drape (unclamped) or PSVC cannula (clamped) to prevent the sound of the clamp from revealing concealment.

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At the time, two different heart-lung machines were used for minimally invasive bypass procedures; either the Jostra HL20 (SOMA Technology Inc., Bloomfield, CT) or the resting heart system (Performer CPB pump, Medtronic, Fridley, MN) based on surgeon preference. To negate the effect of the heart-lung machine, the authors ran two independently powered studies simultaneously. Patients were assigned to one study or the other based on the type of heart-lung machine the surgeon planned to use. Following this, patients were randomized to intervention (clamped PSVC cannula) or control (unclamped PSVC cannula) for each study period as outlined above. A power analysis, assuming an expected mean for BNIR of 63.5% and SD of 6%,[9] the power analysis suggested that 26 patients would be need to detect a change of 6% in the BNIR mean reading during the PSVC clamped period. Therefore, each study (conventional CPB or resting heart CPB) was powered independently to show a difference. Prior to induction, two BNIR monitoring patches were placed on the forehead of patients and adjusted as necessary until readings were acquired from both sides. Baseline data on BNIR (Invos 5100; Somanetics Corporation, Troy, MI) (the 10 minutes immediately prior to the start of the interventions), serum arterial lactate, arterial pH, serum arterial bicarbonate, surgical score and the hemodynamic parameters of central venous pressure (CVP), and blood pressure (BP) were collected (both measured from routinely placed invasive monitors). The surgical score was a four-point Likert scale in which one indicated excellent visualization, two indicated good, three indicated poor, and four indicated extremely poor visualization. The score was determined by the surgeons, both experienced in minimally invasive mitral valve repair, based on the visualization of the mitral valve. The same data were collected at regular intervals (every 5 minutes) during both interventions except for blood work and surgical score, which were collected at the end of each intervention. In addition, baseline demographic data, pump time, cross-clamp time, coldest temperature on pump, intensive care unit (ICU) length of stay, and hospital length of stay were collected. Finally, adverse outcomes data also were collected (death, stroke).

Inclusion criteria were any elective case scheduled to undergo a minimally invasive mitral valve procedure through a right thoracotomy of at least 40 minutes' duration, to allow completion of the study. Patients were excluded if they were younger than 18 or more than 80 years of age, or who had a contraindication to placement of a transesophageal echocardiography (TEE) probe. Randomization was determined through the use of a random number table, in which the order of intervention was placed within a sealed envelope by an individual not directly involved in the data collection or analysis of the trial. Bilateral BNIR monitors were placed prior to induction, while randomization took place immediately prior to the start of the study period. Therefore, patients were excluded from the study if the PSVC was unable to be placed, the TEE probe was unable to be inserted, or if baseline BNIRs were (a) less than 50% or (b) dropped by more than 25% of baseline value.

The conduct of cardiopulmonary bypass was at the discretion of the anesthesiologist, surgeon, and perfusionist according to best clinical practice. All patients had femoral venous access, with a multistage cannula being passed into the SVC (2–3 cm beyond the SVC/right atrial junction) using TEE guidance. A 16-Fr PSVC venous catheter was placed percutaneously through the internal jugular vein using surface ultrasound and transesophageal echocardiographic guidance to guide the cannula to a depth of 8 cm. (Fig 1). The authors routinely observe for PSVC cannulation complications, including venous perforation/mediastinal hematoma, carotid artery cannulation, and accidental venous decannulation. Arterial access was achieved through the use of a 19-or 21-Fr arterial cannula or 8-mm Dacron side graft and access was achieved via the femoral artery or axillary artery. All patients underwent the standard protocol for heparin administration prior to bypass to prevent clot formation within or on the percutaneous venous cannula. This protocol includes: (1) 5,000 units of intravenous heparin after both guidewires are placed in the internal jugular vein and confirmed on ultrasound but prior to cannula insertion; and (2) the use of a solution of 10,000 units of heparin in 1L sodium chloride to slowly flush the PSVC cannula after insertion. All cannulae were placed in a sterile fashion and were contained within the sterile field. Cardiopulmonary bypass was conducted using either the Jostra roller pump with vacuum-assisted venous drainage or with the Medtronic centrifugal pump resting heart circuit with dynamic venous drainage. The perfusionist was free to use vacuum assist, vasopressors, and adjust flows as clinical need dictated.

Data collection started after placement of the left atrial retractor and visualization of the mitral valve to ensure the cannula did not migrate from one study period to the next. After the study period, the PSVC cannula remained unclamped for the remainder of the procedure. All patients went to the cardiac intensive care unit and subsequent management was according to best practices. The trial is registered at clincialtrials.gov #NCT01166841.

RESULTS

A total of 40 patients were approached to take part in both studies. One patient refused consent, giving a total of 39 who consented to participate. Four patients were excluded owing to: Unable to pass the TEE probe in one patient, unable to insert the neck cannula in one patient, and two patients having low BNIRs prior to randomization. This resulted in a total of 28 patients being randomized for the conventional study and seven being randomized in the resting heart study. Two patients (in the conventional study) were unable to complete the PSVC clamped intervention of the trial and the cannula was unclamped early owing to hemodynamic difficulties in one and visualization difficulties in the other. They were included in the analysis as intent-to-treat (Fig 2). As the authors felt that this may favor the use of the PSVC cannula, they also reanalyzed the data without the two patients; however, they found no material differences so data presented are by intent-to-treat only. The baseline characteristics, ICU and hospital length of stay are presented in Table 1. The intraoperative data are presented in Table 2.

For the resting heart system ($n = 7$) the study was terminated early, due to discontinuance of routinely using this system for minimally invasive mitral valve cases. The authors were, therefore, underpowered to show differences in outcomes between the conventional bypass circuit and the minicircuit.

For the conventional bypass group ($n = 28$), for the primary outcome of BNIRs there were no differences between the two interventions (PSVC clamped 55.0% ± 11.6% versus control 56.1% ± 10.2%) ($p = 0.283$). The secondary outcomes are presented in Table 3. Of note, the outcomes for pH (PSVC clamped 7.35 ± 0.05 versus 7.37 ± 0.05 $p = 0.015$), surgical score (PSVC clamped 1.96 ± 1.14 versus 1.22 ± 0.51 $p = 0.002$) and CVP (PSVC clamped 11.6 mmHg ± 4.8 mmHg versus 6.1 mmHg ± 6.1 mmHg $p < 0.001$) were significantly different. Averages of the left and right BNIRs were used for determining the primary outcome. Differences between the left- and right-sided BNIRs averaged 5% during the intervention, with a range from 0.3% to 16%. Higher values were recorded on the right side in 21 of 35 patients (both studies combined).

There were no direct complications attributable to clamping the PSVC cannula. Complications related to the surgical procedure included: One patient who suffered a liver laceration