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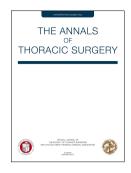
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Right axillary thoracotomy in congenital cardiac surgery: analysis of percutaneous cannulation

Running head: Right axillary thoracotomy: ASD to CAVSD

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Abstract

Background: Vertical right axillary mini-thoracotomy (VRAMT) represents a minimalinvasive and cosmetically attractive alternative for selected congenital heart defects. We report our institutional experience with VRAMT, especially regarding the performance of percutaneous femoral venous access to establish extracorporeal circulation in this pediatric population.

Methods: Retrospective single center analysis of children up to 16 years who underwent corrective cardiac surgery using VRAMT over a period of 5 years. VRAMT involved a 4-5 cm vertical incision parallel to the anterior axillary fold and aortic/bicaval cannulation. Since 2016, the technique has been modified and the inferior-vena-cava was cannulated using femoral percutaneous-venous-access. The primary endpoints were all-cause mortality with additional secondary endpoints of major adverse cardiac and cerebrovascular events (MACCE) and conversion to median sternotomy.

Results: A total of 110 patients with biventricular congenital malformations were included. Age was 2.3 (0.2-16) years and body weight was 11 (3-47) kg. Extracorporeal-circulationtime was 66 (24-167) minutes, cross clamp time was 41 (9-95) minutes. Fast-trackmanagement with on-table extubation was achieved in 34.5% (n=38). For patients with percutaneous-femoral venous-cannulation (n=38, 34.5%), thrombosis at the cannulation site was recorded in 5 (13.5%) cases. There was no early or late mortality during the follow-up of 14.4 (0.8 – 47.19) months. No wound infection nor thoracic deformities were observed.

Conclusions: VRAMT can be considered as an alternative, minimal-invasive and cosmetically attractive access for the repair of frequent congenital heart defects in newborns and young children. Percutaneous-femoral-venous cannulation provides sufficient ECC flow and can be used even in infants with early postoperative heparin prophylaxis.

Abbreviations

- ASD atrial septal defect
- BH beating heart
- BMI body mass index
- BSA body surface area
- CAVSD complete atrioventricular septal defects
- CL cardioplegia line
- DCRV double chambered right ventricle
- ECC extracorporeal circulation circuit
- FR french scale system
- IVC inferior vena cava
- MACCE major adverse cardiac and cerebrovascular events
- MI myocardial infarction
- MS median sternotomy
- PAVSD partial atrioventricular septal defects F
- PAPVC partial anomalous pulmonary venous connection
- PFO persistent foramen ovale
- PLSVC persistent left superior vena cava,
- MS median sternotomy
- REDCap research electronic data capture
- SVC superior vena cava
- TEE transoesophageal-echocardiography
- VRAMT vertical-right-axillary-mini-thoracotomy
- VSD ventricular septal defects

After the first successful intracardiac correction of an atrio-septal defect by Lewis and Varco in 1952, surgical methods have become safer and with increasing technological possibilities, the urge for minimal invasive operations has reached the domain of cardiac surgery [1,2].

Median sternotomy has been the gold standard to perform open cardiac surgery for the repair of congenital heart defects in the past. This access is considered as rather invasive, it results in a well visible scar on the midline of the chest. Especially in growing children, the resulting stigma of being a "heart patient" can lead to long lasting psychological distress [3-5].

Several different accesses to the heart have been assessed such as partial sternotomy [6,7], anterolateral thoracotomy [8,9], and posterior thoracotomy [10,11]. As for the anterolateral thoracotomy however, an impairment of breast development especially when performed in pre-pubescent females has been noticed and this access has therefore been considered suboptimal for these particular patients [12].

In order to perform surgery without increased risk and to achieve a satisfactory surgical outcome, site and length of the incision must allow sufficient access to the surgical field.₇ Ideally, central arterial cannulation should be performed in order to avoid potential vascular complications observed following femoral artery cannulation especially in smaller infants. As described before, a right axillary incision exposes sufficiently the right atrium and right heart structures as needed for the repair of some of the congenital heart defects [3,13].

The reporting institution started to perform closure of atrial septal defects by access through a vertical right axillary mini-thoracotomy (VRAMT) in 2010. Given the convincing results the VRAMT access was stepwise expanded to more complex cardiac defects. In 2014 surgical correction of complete atrio-ventricular septal defects (CAVSD) through VRAMT was initiated, which has not been described in literature before [14].

This report analyzes the perioperative outcomes of VRAMT for the correction of a variety of congenital cardiac defects. Furthermore, the study includes an analysis of percutaneous femoral vein cannulation and of the extracorporeal circulation (ECC) performance in relation to body surface area.

Patients and Methods

Patient selection and data collection

A cardiosurgical database search (January 2012 until December 2018) was conducted and patients <16 years of age with the following preoperative diagnosis undergoing VRAMT were identified: atrial septal defect (ASD), ventricular septal defect (VSD), partial atrioventricular septal defects (PAVSD), complete atrioventricular septal defects (CAVSD), partial anomalous pulmonary venous connection (PAPVC), double chambered right ventricle (DCRV) and cor tri-atriatum. Patient with a concomitant diagnosis of patent ductus-arteriosus (PDA), unbalanced AVSD, severe atrioventricular valve regurgitation and left persistent caval vein were excluded. All surgical procedures were performed by the same surgeon (AK). An observational study design was used following the STROBE statement [15]. All data were gathered in a standardized database using the Research-Electronic-Data-Capture (REDCap) system. Patient characteristics, procedural data and outcomes are presented in Tables 1-3.

Preoperative diagnosis were made by transthoracic echocardiography and for intraoperative assessment with transesophageal echocardiography (TEE). The peri- and postoperative diagnostics included clinical examination and trans-thoracic echocardiography. As for the follow up, data regarding clinical status, wound complications, thorax deformities, surgical result, and residual lesions were extracted from the electronic patient charts. All statistical calculations were performed using Stata 12 (StataCorp LLC, College Station, Texas, USA). Data are presented as mean with standard deviation (SD) or median with range [lowest value–highest value] depending on data distribution. The study was approved by the cantonal ethics committee.

Patient selection for VRAMT

For several years, VRAMT has been the standard approach for repair of secundum ASD, sinus venous defect, partial-anomalous-pulmonary-venous-return, partial atrioventricular septal defects. Given the growing institutional experience with this cosmetically appealing and less invasive approach, and its comparable results to the standard access the median sternotomy, our group extended its use, since 2012, to perimembranous VSD repair [14]. Furthermore since 2014 the VRAMT approach was used for correction of CAVSD with a Rastelli classification type A [14].

Follow up

The follow-up included ambulatory visits with physical examination and echocardiography by senior pediatric cardiologists at one, three and six months postoperatively and yearly

thereafter. All follow-up data were included in the analyses. For the purpose of this study, all echocardiographic data at discharge and the most recent follow-ups are included.

Definition of major adverse cardiac and cerebrovascular events

Major adverse cardiac and cerebrovascular events (MACCE) were defined as sudden cardiac death, myocardial infarction (MI), cardiac arrhythmias needing intervention with permanent pacemaker implantation, neurological complications, or renal failure requiring replacement therapy. Myocardial infarction was defined according to the Third Universal Definition of Myocardial Infarction by the European Society of Cardiology Guidelines as elevation of cardiac high-sensitive troponin (hs-cTnT) >10 x 99th percentile in patients with normal baseline hs-cTnT levels [16].

Surgical technique

Patients received general anesthesia with endotracheal intubation after induction with sevoflurane, sufentanil and rocuronium. Intraoperative monitoring followed American Society of Anesthesiologists standard monitoring including invasive arterial and central venous pressure, near-infrared spectroscopy and tranesophageal echocardiography. Additionally, a peripheral venous catheter sheath (Size: 4 Fr.) was inserted in the right femoral vein using ultrasound guidance if percutaneous venous cannulation was planned (Figure 1 A). The anterior, posterior axillary line and 4th intercostal space were outlined in supine position with arms in adduction and patients were placed in a left decubitus position. Following lateral positioning of the child the arm was elevated to expose the axillary region (Supplemental Video 1).

A vertical incision of 4-5 cm parallel to the right anterior axillary fold was performed overlying the 4th or 5th-intercostal-space. The subcutaneous tissue was generously mobilized. The serratus anterior muscle overlying the 4th-intercostal-space was identified and the lateral border of the pectoral muscle slightly mobilized. Care was taken to avoid injury to the long thoracic nerve and artery lying posteriorly on the serratus anterior muscle. Thoracotomy was performed at the superior margin of the 5th-rib in the 4th intercostal space. A retractor (*Fehling Instruments,* Karlstein, Germany) was selected according to patient weight: 3-7 kg: V-CUT Titanium MSX-1, 7-15 kg: MSX-2) (Figure 1 A). The pericardium was opened 1.5 - 2 cm anterior to the phrenic nerve. Stay sutures were placed along the margins of the pericardium and fixed to the surrounding drapes to retain the lungs (Figure 1 B).

Extracorporeal circulation (ECC) was established following cannulation of the ascending aorta and vena cava superior and inferior (Figure 2). An indexed perfusion flow of 2.7

l/min/m² (BSA) at normothermia (36° Celsius) was defined as optimal ECC flow [17]. The inferior vena cava was either cannulated directly or in patients >5kg a percutaneous venous cannula (BIO-MEDICUS, Medtronic: Pediatric-Venous-Cannulae Sizes 8-14Fr. / Bio-Medicus NextGen Femoral Venous Cannulae 15-25 Fr) was inserted into the femoral vein using Seldinger technique (Supplemental Video 1).

For interventions with aortic cross-clamping a left ventricular vent and ascending aortic root vent were placed. ECC was conducted in mild hypothermia. CO2 insufflations into the thoracic cavity ware routinely applied. The correction of ASD and PAPVC were performed in induced ventricular fibrillation for the majority of cases.

For all other procedures, the aorta was cross-clamped and antegrade cardioplegia was administered by using a low-dose (1.5 ml/kg), single-shot crystalloid solution (Cardio-plexol[™], Swiss Cardio Technologies AG, Switzerland) [18]. The surgical repair of the congenital cardiac defects through VRAMT followed standard techniques (Video 1).

Deairing was performed via a left ventricular vent and the aortic root vent. During rewarming epicardial electrodes for temporary pacing were placed to the right atrium and ventricle. Following central decannulation and protamine administration, the peripheral percutaneous venous cannulas was removed, and hemostasis was achieved by manual compression for at least 10 minutes. The pericardium was closed except for a distal opening (1-2 cm) allowing drainage of pericardial fluid into the right pleural space. A subpleural paravertebral catheter was placed covering two segments each cranial and caudal to the VRAMT interspace for postoperative pain management. A standard solution of bupivacaine 0.125% was continuously infused for up to 72 hours. Two chest drains were inserted, and the chest was closed with absorbable suture material (Supplemental Video 1).

Results

Patient characteristics and preoperative data

A total of 110 patients (55 female) were included in the study (Table 1). Overall age was at a median of 2.3 (02-16) years and a median weight of 11 kg (3-47). Median body surface area of all patients was at a median of 0.5 (0.2-1.5) m². Gender distribution was equal with 55 females (50%). Non-cardiac diagnosis included genetic disorders (n=18, of which 11 with Trisomy 21), neurological disorders (n=3), metabolic disorders (n=8), urogenital disorders (n=5), pulmonary hypertension (n=7). and failure to thrive (n=17).

Intraoperative Data and Assessment

In all patients the correction could be performed through the right axillary minimal invasive access, there was no need for conversion to a different approach. Intraoperative data and cardiopulmonary bypass characteristics are listed in Table 2. Concomitant procedures in the VSD group included ASD closure with direct suture (n=15), tricuspid valve reconstruction (n=24), and PFO closure (n=1). One patient with PAVSD underwent right atrio-ventricular valve reconstruction.

Percutaneous venous cannulation

Thirty-eight patients (35%) underwent percutaneous-femoral-venous cannulation. In one early case femoral venous cannulation was intended but overall drainage was too low, and a switch to central cannulation was performed. Cannula sizes related to the Body Surface Area of the patients are shown in Figure 3. The optimal calculated and achieved ECCflow rates at normothermia (36°Celcius) for patients with percutaneous-femoral-venous cannulation (n=38) of the inferior vena cava are plotted in Figure 4. The optimal calculated ECC flow at normothermia was achieved when the percutaneous-transfemoral-venous cannula size was equal to or smaller than SVC venous cannula size. Oversizing of the percutaneous-femoral-venous-femoral-venous cannula size was normothermia lead to decreased ECC flow (Figure 4. Arrows).

Postoperative Assessment

Postoperative data are presented in Table 3. Starting in 2016, fast-track management with on-table extubation was performed whenever possible

There were no major adverse cardiac and cerebrovascular events (MACCE). Postoperative complications included pneumonia (n=2) and the need of permanent pacemaker implantation for complete heart block in a patient with CAVSD (n=1). Overall, the median hospital length of stay was at seven (4-31) days. There was no case of 30-day mortality.

For patients with percutaneous-femoral-venous cannulation (n= 38, 35%), thrombosis at the cannulation site in the right femoral vein was detected in five (13.5%) cases (Figure 3) postoperatively by ultrasound. In patients with a BSA <0.3m2 venous thrombosis at the cannulation site was most common with the use of a 12 French percutaneous-venous cannula was used (Figure 3).

Anticoagulation therapy was initiated with unfractionated heparin. Heparin infusion rate was maintained according to anti-Xa activity of 0.3 - 0.5 U/mL. There were no cases of persistent thrombosis at the cannulation site. All patients were examined clinically and with vascular

ultrasound before discharge. There was no case of bleeding, nor was any surgical intervention at the peripheral cannulation site needed.

Follow up

Follow-up is complete with a median follow up time of 14.4 (0.8 - 47.19) months, respectively. Follow-up data include the results of a transthoracic echocardiography at discharge from the hospital and the findings of the last clinical checkup at ambulatory patient visit. Ambulatory follow up visits included clinical examinations as well as echocardiography. There have been no cases of late mortality. The latest echocardiographic follow-up data are presented in Supplemental Table 1.

In the follow-up period, surgical re-intervention was necessary in one patient with CAVSD. The patient underwent reoperation due to a new severe left atrio-ventricular valve insufficiency that had not been observed at the end of the index procedure. The reoperation was performed through the previous VRAMT access. The dysfunction was caused by a suture detachment of the cleft closure. The patient was reoperated by re-reconstruction of the left atrio-ventricular valve. The patient had an uneventful further postoperative course.

Comment

The ongoing general strategy for less invasive procedures has increased the quest for minimally invasive accesses, also in the field of corrective heart surgery. Several publications have shown that less invasive thoracic incisions can be safely applied for the correction of simple congenital heart defects in pediatric patients [3,5,13,19]. The right axillary mini-thoracotomy was developed to improve the cosmetic results while allowing equal surgical outcome for corrective heart surgery (e.g. ASD) [3,14].

Following the original institutional experience with vertical right axillary mini thoracotomy for the correction of simple congenital heart defects, the technique of VRAMT was transferred to more complex cardiac malformations. Nowadays VRAMT has become the standard procedure for the correction of atrial and ventricular septal defects, partial and complete atrio-ventricular septal defects (Rastelli type A), partial anomalous pulmonary venous return, double chambered right ventricle, and cor triatriatum.

As far as aortic cross-clamp times, cardiopulmonary bypass time and operation time are concerned, VRAMT procedures are comparable to standard median sternotomy, indicating an adequate exposure and access to the required anatomical structures [14]. Furthermore, VRAMT procedures can be performed using standard instruments for access and the

correction itself. These findings confirm previously reported advantages and results by other groups [4,5,13,20,21].

As described in our series, 50% of the patients are female; this emphasizes the need for a surgical access that spares developing breast tissue. Furthermore, no later impairment of breast development was observed, neither did any of the patients suffer from thorax deformity during growth.

Optimal surgical exposure is crucial for the assessment and correction of cardiac malformations while cardiopulmonary bypass installations take up space in the already minimized surgical operative field. The cannulation of femoral vessels reduces this problem but may be followed by thrombotic complications when small vessels are considered. Previous studies have described various complications after peripheral vessel cannulation, especially for arterial vessels in neonates and small children, thus the indication for this method has to be carefully evaluated in every patient [13,20].

Percutaneous peripheral cannulation of the femoral vein has been performed in all patients since 2016 for VRAMT, while the aortic cannula and SVC cannula are placed centrally. The IVC drainage through a peripheral cannulation improves the surgical access and increases the view to the more caudal structures, for instance in the correction for CAVSD. Furthermore, potential complications and compromises due to cannulation of rather small femoral arteries with cannulas, large enough to provide adequate ECC perfusion in mild hypothermic bypass, can be avoided. Femoral artery cannulation has led to access site complications in other studies and should therefore be performed only with limited indication and meticulous technique.

Nevertheless, we recorded five cases of early thrombosis (<24h) at the cannulation site in the right femoral vein in the initial period after starting percutaneous femoral vein cannulation. Retrospectively, it appears that this complication was mostly due to an oversizing of the cannula size. Since we routinely adopted postoperative prophylactic antithrombotic therapy by unfractionated heparin treatment, these complications have not reoccurred.

Furthermore, we analyzed the percutaneous venous cannula sizes in relation to the body surface area of the patients. Purpose for this analysis is based on the situation that the percutaneous femoral cannulas have a different design to the standard cannulas. In contrast, these cannulas are much longer with multiple drainage ports and allow more adequate

drainage at smaller diameters. The optimal calculated ECC flow at normothermia was achieved when the percutaneous-transfemoral-venous cannula size was equal to or smaller than SVC venous cannula size. Oversizing of the percutaneous-femoral-venous cannula lead to decreased ECC flow with suction events. We could demonstrate that in patients with a BSA of $<0.3m^2$ a 8 Fr. percutaneous venous cannula provides sufficient hemodynamic performance.

The only reoperation was needed in one patient who received correction of CAVSD due to a dehiscence of the cleft suture. The reoperation of the patient could be performed through the previous incision site and re-reconstruction of the valve 42 days after the initial correction. We believe that the routine closure of the pericardium is advantageous in regard to potential re-interventions. The postoperative course was uneventful.

Conclusion

This study confirms previous reports that described VRAMT as a feasible and efficient approach for surgical repair of congenital heart defects with cosmetically favorable results and with comparable surgical results to median sternotomy. Cardiopulmonary bypass can be performed without peripheral arterial cannulation while percutaneous femoral vein cannulation provides sufficient ECC flow. The latter can be safely applied even in smaller infants, but early postoperative heparin prophylaxis is recommended.

Limitations

The patient collective is relatively small, especially for less frequent malformations. Since VRAMT is the standard approach for many heart defects and the overall case number is small, there was no control group. However, the fact that all cases were performed by the same surgeon and surgical team provides an adequate consistency of technique and quality of the surgical correction.

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Diagnosis	n	Age (years)	Weight (kg)	Height (cm)	Body Surface Area (m ²)
ASD II°	35 (32%)	5.58 (0.5-16)	18.5 (5-47)	110 (64-155)	0.7 (0.3-1.4)
VSD	44 (40%)	0.55 (0.2-15)	7.1 (3-39)	69 (54-154)	0.4 (0.2-1.3)
CAVSD	12 (11%)	0.51 (0.2-1.3)	5.8 (4.3-9.1)	67 (50-76)	0.3 (0.2-0.4)
PAVSD	7 (6%)	2.9 (0.75-6)	10 (9-18)	91 (73-120)	0.5 (0.4-0.8)
PAPVC	9 (8%)	4.9 (2-12)	17 (9-47)	107 (86-159)	0.7 (0.5-1.5)
DCRV	1 (1%)	1.00	12.00	79.00	0.49
Cor Tria- triatum	2 (2%)	4.9 (2-7)	13 (9-17)	97 (8-114)	0.6 (0.4-0.7)
Total	110	2.3 (0.2-16)	11 (3-47)	85 (50-159)	0.5 (0.2-1.5)

Table 1: Patient demographic data. Data are n (%) or median (min-max), unless otherwise indicated. ASD II°: secondary atrio-septal defects, CAVSD: complete atrio-ventricular septal defects, DCRV: double chambered right ventricle PAVSD: partial atrio-ventricular septal defects, PAPVC: partial abnormal pulmonary venous connection, VSD: ventricular-septal defects.

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Diagnosis	n	Surgical time (min)	ECC time (min)	X-clamp time (min)	BH (n)	PVC (n)
ASD II°	35 (32%)	125 (83-210)	42 (24-115)	14 (9-20)	32	17
VSD	44 (40%)	159 (120-238)	76 (54-140)	41 (21-67)	0	15
CAVSD	12 (11%)	189 (110-212)	106 (66-139)	64 (37-73)	0	2
PAVSD	7 (6%)	155 (113-220)	75 (46-167)	42 (21-95)	0	1
PAPVC	9 (8%)	150 (70-180)	59 (27-80)	39 (38-41)	7	3
DCRV	1 (1%)	110.00	56.00	28.00	0	0
Cor Tria- triatum	2 (2%)	155 (150-160)	86 (85-87)	42 (39-46)	0	0
Total	110	150 (70-238)	66 (24-167)	41 (9-95)	39	38

Table 2: Intraoperative Data. Data are n (%) or median (min-max), unless otherwise indicated. ASD II°: secondary atrio-septal defects, BH: Beating heart, Cross-lamp time of the aorta, CAVSD: complete atrio-ventricular septal defects, DCRV: double chambered right ventricle, ECC: Extracorporeal circulation, PAVSD: partial atrio-ventricular septal defects, PAPVC: partial abnormal pulmonary venous connection, PVC: Peripheral inferior vena cava cannulation, VSD: ventricular-septal defects.

Diagnosis	Total (n)	Extubation in OR (n)	Time on ventilator (h)	ICU length of stay (h)	Hospital length of stay (d)
ASD II°	35 (32%)	18	4 (2-24)	48 (20-110)	6 (4-18)
VSD	44 (40%)	12	20 (3-96)	72 (3-259)	8 (5-21)
CAVSD	12 (11%)	0	32.5 (2-12)	123 (45-288)	12 (8-31)
PAVSD	7 (6%)	2	6 (3-20)	45 (23-70)	6 (4-7)
PAPVC	9 (8%)	5	4 (2-11)	50 (24-147)	5 (4-9)
DCRV	1 (1%)	0	8.00	49.00	7.00
Cor Triatriatum	2 (2%)	1	10 (3-18)	21 (18-24)	5.5 (5-6)
Total	110	38	8 (2-96)	66 (3-288)	7 (4-31)

Table 3: Postoperative data. Data are n (%) or median (min-max), unless otherwise indicated. ASD II°: secondary atrio-septal defects, CAVSD: complete atrio-ventricular septal defects, DCRV: double chambered right ventricle ICU: intensive care unit OR: operation room, PAVSD: partial atrio-ventricular septal defects, PAPVC: partial abnormal pulmonary venous connection, VSD: ventricular-septal defects.

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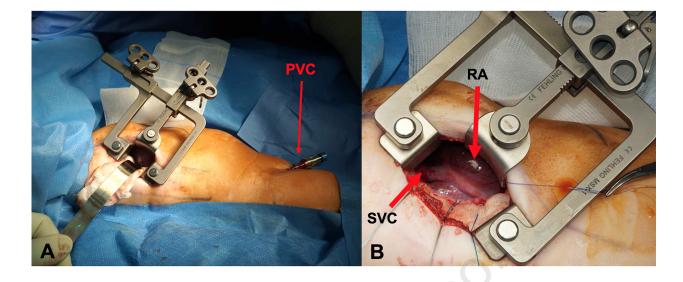
Figure Legends

Figure 1: A. Placement of patients in a left decubitus position with surgical access site and peripheral-venous-catheter-sheath (PVC) in right femoral vein. B. Visualization of the right atrium (RA) and superior vena cava (SVC).

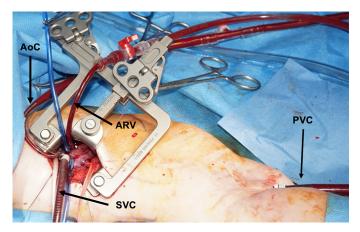
Figure 2: Direct aortic cannulation (AoC), superior vena cava (SVC) and placement of aortic root vent (ARV). The inferior vena cava was cannulated using percutaneous-venous cannulation (PVC) technique.

Figure 3: Femoral venous cannula sizes in relation to Body-Surface-Area. Patients with postoperative thrombosis are marked in red. Fr: French scale system

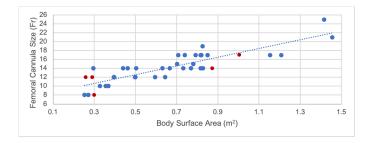
Figure 4: Venous Cannula Sizes (FR) in relation to Body Surface area and maximal achieved perfusion flow (I/min) versus, optimal calculated flow for extracorporeal circulation circuit at normothermia. Arrows show decreased ECC flow. Fem Cannula: Femoral Cannula, FR: French, SVC: superior vena cava

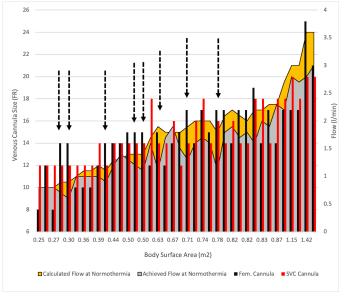


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