Surgical repair of descending thoracic and thoracoabdominal aortic aneurysm involving the distal arch: Open proximal anastomosis under deep hypothermia versus arch clamping technique

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Background: Surgical repair of a descending thoracic and thoracoabdominal aortic aneurysm (DTA/TAAA) involving the distal arch is challenging and requires either deep hypothermic circulatory arrest (DHCA) or crossclamping of the distal arch. The aim of this study was to compare these 2 techniques in the treatment of DTA/ TAAA involving the distal arch.

Methods: From 1994 to 2012, 298 patients underwent open repair of DTA/TAAA through a left thoracotomy. One hundred seventy-four patients with distal arch involvement who were suitable for either DHCA (n = 81) or arch clamping (AC; n = 93), were analyzed. In-hospital outcomes were compared using propensity scores and inverse-probability-of-treatment weighting adjustment to reduce treatment selection bias.

Results: Early mortality was 11.1% in the DHCA group and 8.6% in the AC group (P = .58). Major adverse outcomes included stroke in 16 patients (9.2%), low cardiac output syndrome in 15 (8.6%), paraplegia in 10 (5.7%), and multiorgan failure in 10 (5.7%). After adjustment, patients who underwent DHCA were at similar risk of death (odds ratio [OR], 1.14; P = .80) and permanent neurologic injury (OR, 0.95; P = .92) to those who underwent AC. Although prolonged ventilator support (>24 hours) was more frequent with DHCA than with AC (OR, 2.60; P = .003), DHCA showed a tendency to lower the risk of paraplegia (OR, 0.15; P = .057).

Conclusions: Compared with AC, DHCA did not increase postoperative mortality and morbidity, except for prolonged ventilator support. However, DHCA may offer superior spinal cord protection to AC during repair of DTA/TAAA involving the distal arch. (J Thorac Cardiovasc Surg 2014;148:2101-7)

Open surgical repair of a descending thoracic aortic and thoracoabdominal aortic aneurysm (DTA/TAAA) involving the distal arch is challenging because simple proximal DTA crossclamping is not always possible and either deep hypothermic circulatory arrest (DHCA) or clamping of the aortic arch may be required to achieve proximal anastomosis.^{1,2} The advantages of DHCA are cited as excellent protections for the spine and visceral organs, a bloodless field, and no need for aortic crossclamping.³⁻⁵ Conversely, more time is required to decrease and increase the body temperature, as a result of which the risk of coagulopathy, systemic inflammatory response, cold pulmonary and myocardial damage, and left ventricular distention injury may be increased.^{6,7} Moreover, with the advancements in

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various cardiopulmonary bypass (CPB) strategies and adjunct procedures for distal organ protection under mild or moderate hypothermia, profound hypothermia is no longer the only option for distal organ protection.⁸⁻¹⁰ However, when the aneurysm involves the distal arch, arch clamping (AC) is the only viable alternative to DHCA. The AC technique is also controversial, however, because gaining proximal control of the aorta between the great vessels is often challenging and requires extreme caution in handling the aortic arch, especially in the presence of a "shaggy aorta."^{11,12} Furthermore, temporary occlusion of the left subclavian artery (LSCA) may potentially reduce spinal cord perfusion and increase the risk of spinal cord ischemic injury.^{11,13} There is currently no consensus on the optimal method for proximal control in open repair of DTA/TAAA involving the distal arch, and previous studies on this topic have been limited. Thus, the aim of this study was to compare the clinical outcomes of DHCA versus AC in the surgical repair of DTA/TAAA involving the distal arch.

METHODS Patients

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Abbreviations and Acronyms			
AC	= arch clamping		
CI	= confidence intervals		
CPB	= cardiopulmonary bypass		
CSF	= cerebrospinal fluid		
CT	= computed tomography		
DHCA	= deep hypothermic circulatory arrest		
DTA/TAAA	A = descending thoracic and		
	thoracoabdominal aortic aneurysm		
LSCA	= left subclavian artery		
LV	= left ventricle		
SVG	= saphenous vein graft		

arch and allowed proximal DTA clamping were excluded. Distal arch involvement was defined as an aneurysm occurring at the isthmus level or one that involved the distal arch (Figure 1), so that simple crossclamping of the proximal DTA was impossible. Fifty-one patients with distal arch involvement for whom there was no alternative but to use DHCA were also excluded. Thus, 174 patients in whom either DHCA or AC was deemed possible were included in this study; 81 patients underwent DHCA and 93 patients underwent AC. The 174 procedures in this study were performed by 5 different surgeons. The use of the DHCA technique for each surgeon was as follows; A (46 of 86; 53.5%), B (7 of 27; 25.9%), C (4 of 26; 15.4%), D (17 of 23; 73.9%), and E (7 of 12; 58.3%). Some surgeons have favored open proximal anastomosis under DHCA, and others have tried to crossclamp the arch by any means possible. For extensive TAAA disease regardless of distal arch involvement, some surgeons preferred DHCA, based on the belief that profound hypothermia might offer superior protection to the spinal cord and distal organs. The choice of DHCA versus AC was primarily at the attending surgeon's discretion.

The present study protocol was approved by the ethics committee and institutional review board of our institution, and informed consent from individual patients was waived because of the retrospective nature of the study.

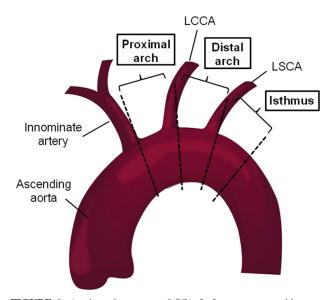


FIGURE 1. Aortic arch anatomy. *LCCA*, Left common carotid artery; *LSCA*, left subclavian artery.

Operative Technique

Patients were intubated with a double-lumen endotracheal tube. All procedures were performed through a left posterolateral thoracotomy or a thoracoabdominal approach via the fifth or sixth intercostal space. The DTA and abdominal aorta were dissected free to allow proximal and distal crossclamping and resection of the pathologic segments. The left femoral artery and vein were exposed through an oblique incision in the inguinal crease. After heparin sodium (3 mg/kg) was administered, arterial and venous cannulation was established with a wire-directed approach. Transesophageal echocardiography was used to monitor the placement of the venous catheter in the right atrium. Vacuum-assisted venous drainage was used and additional cannulation was applied through the pulmonary artery when the flow was insufficient.

DHCA was used in 81 patients (46.6%) and AC was used under partial femoro-femoral CPB in 93 patients (53.4%). Of the 81 patients who underwent DHCA, the lowest nasopharyngeal temperature was 12 to 15°C in 28 (34.6%), 15 to 18°C in 33 (40.7%), and 18 to 22°C in 20 (24.7%). In the early period, surgeons preferred severe profound hypothermia based on the belief that it could provide superior protection to the spinal cord or other end organs. Recently, however, even surgeons who prefer DHCA for proximal control in our institution usually aim for a nasopharyngeal temperature not lower than 20 to 24°C, because proximal anastomosis takes 15 to 20 minutes. A left atrial (LA) vent through the left superior or inferior pulmonary vein was used in 36 (44.4%) patients in the DHCA group, and cardioplegia was not used. When the desired nasopharyngeal temperature was reached, circulatory arrest was initiated and the aorta was opened. Proximal aortic anastomosis was performed with a branched vascular graft in an open fashion without any selective antegrade cerebral perfusion techniques, after which extraarterial cannulation was added through the side branch of the graft so that dual perfusion to both the upper and lower body could be achieved. After placing a crossclamp distal to the side branch, partial CPB flow to the upper body was reinstituted. During the open proximal anastomosis under DHCA, the patient was placed in the Trendelenburg position, and while reinstituting upper body perfusion via the sidearm branch of the graft, the deairing procedure was performed at the same time, shortly before completing the proximal anastomosis.

In the AC group, the body temperature was lowered to 30 to 35° C. Distal arch and separate LSCA clamping was conducted with beating-heart status. After proximal anastomosis, crossclamping was moved proximal to the graft. Distal anastomosis was performed in an open fashion when distal clamping was not feasible. When aortic replacement involved a visceral or renal segment, visceral/renal perfusion with cold blood was performed using separate balloon cannulas. After completion of the anastomoses, full CPB was resumed to both the upper and lower body. Cerebrospinal fluid (CSF) drainage was used routinely as an adjunct for spinal protection when the disease involved the aorta at the level between the T8 and L2 vertebrae (n = 105, 60.3%).

Statistical Methods

Categorical variables are presented as frequencies and percentages, and continuous variables are expressed as the mean \pm standard deviation or the median with the range. Differences in baseline characteristics were compared using the unpaired *t* test or Mann-Whitney *U* test for continuous variables, and the χ^2 test or the Fisher exact test for categorical variables, as appropriate. To reduce the impact of treatment selection bias and potential confounding in this observational study, we robustly accounted for significant differences in patient characteristics using weighted logistic regression analysis and inverse probability of treatment weighting.¹⁴ With this technique, weights for patients undergoing DTA/TAAA repair using DHCA were the inverse of the propensity scores, and weights for patients using the AC technique were the inverse of 1 – propensity scores. Stabilized weights were used to reduce the weights of treated patients with low propensity scores and untreated patients with high propensity scores.¹⁵ Propensity scores were estimated by multiple logistic regression analysis.

All prespecified covariates were included in full nonparsimonious models for DHCA versus AC (Table 1). The model was well calibrated (Hosmer-Lemeshow test; P = .46) with reasonable discrimination (C statistic = .70). Results are expressed as odds ratios (OR) with 95% confidence intervals (CI). All reported *P* values are 2-sided. Statistical analyses were performed with SPSS version 18.0 (IBM Corp, Armonk, NY).

RESULTS

The unadjusted and adjusted baseline characteristics of the patients are shown in Table 1. There were no statistical differences in aortic diseases, rupture, shock, and emergency surgery between the 2 groups. The proportion of Crawford type I replacements was slightly higher in the AC group (20.4% vs 9.9%, P = .055), but after adjustment, the patient distribution was well balanced (P = .99). The rate of CSF drainage was also similar between the 2 groups. Concomitant coronary artery bypass grafting procedures were performed in 4 patients with the following anastomoses details: saphenous vein graft (SVG) to the left anterior descending artery in 1, SVG to the obtuse marginal branch in 1, and SVG to the posterior descending artery in 2. The origins of the inflow were a descending thoracic aortic graft in 2 cases and native descending thoracic aorta in 2 cases.

The unadjusted early postoperative outcomes are summarized in Table 2. The early death rate was 9.8% overall; 11.1% in the DHCA group and 8.6% in the AC group, with no significant intergroup statistical difference (P = .58). The major complication rates were 38.3% and 31.2% in the DHCA and AC groups, respectively (no significant difference, P = .33). The incidence of low cardiac output syndrome showed a tendency to be higher in the DHCA group, but the difference was not significant (12.3% vs 5.4%, P = .11). The stroke rate was similar in both groups; however, the paraplegia rate was significantly higher in the AC group (9.7% vs 1.2%, P = .017), and prolonged mechanical ventilation was required more frequently in the DHCA group (74.1% vs 49.5%, P = .001).

TABLE 1. Patient profiles at baseline

	Unadjusted data			Data adjusted by IPTW		
	DHCA	AC		DHCA	AC	
Characteristics	(N = 81), n (%)	(N = 93), n (%)	P value	(N = 81), n (%)	(N = 93), n (%)	P value
Age (y), mean \pm SD	53.2 ± 12.9	54.1 ± 14.2	.65	53.6 ± 12.6	53.5 ± 14.3	.97
Female	20 (24.7)	15 (16.1)	.16	19.8	19.4	.95
Diabetes mellitus	3 (3.7)	8 (8.6)	.19	4.9	6.5	.75
Hypertension	43 (53.1)	52 (55.9)	.71	54.3	53.8	.94
Disease of the aorta			.13			.96
Aneurysm	32 (39.5)	49 (52.7)	.10	46.9	47.3	.96
Chronic dissect	42 (51.9)	34 (36.6)	.05	44.4	43.0	.85
Acute dissect	7 (8.6)	10 (10.8)	.80	8.6	9.7	.81
Rupture	6 (7.4)	7 (7.5)	.98	6.2	6.5	.94
Malperfusion	2 (2.5)	1 (1.1)	.48	1.2	1.1	.92
Shock	0 (0)	1 (1.1)	.35	0	1.1	.53
Hemothorax	4 (4.9)	4 (4.3)	.84	3.7	4.3	.84
Urgent/emergency	8 (9.9)	8 (8.6)	.77	8.6	8.6	.99
Extent of surgery			.15			.84
Descending thoracic aorta only	47 (58.0)	50 (53.8)	.57	54.3	54.8	.95
Descending thoracic segments			.17			.95
Proximal third (A)	17 (21.0)	25 (26.9)	.38	18.5	18.3	.97
Proximal two thirds (AB)	14 (17.3)	10 (10.8)	.27	16.0	14.0	.83
Entire descending thoracic (ABC)	16 (19.8)	15 (16.1)	.56	21.0	22.6	.80
Thoracoabdominal aorta						
Crawford type I	8 (9.9)	19 (20.4)	.055	16.0	16.1	.99
Crawford type II	26 (32.1)	24 (25.8)	.36	29.6	29.0	.93
Left ventricular ejection fraction (%), mean \pm SD	61.6 ± 5.6	61.0 ± 5.4	.52	61.1 ± 5.8	61.2 ± 5.3	.87
Preoperative aortic regurgitation	26 (32.1)	20 (21.5)	.11	24.7	24.7	.99
GFR (mL/min/1.73 m ²), mean \pm SD	81.8 ± 26.7	81.5 ± 34.3	.95	82.4 ± 25.2	82.1 ± 33.5	.95
Cerebrospinal fluid drainage	50 (61.7)	55 (59.1)	.73	65.4	62.4	.75
SIA reattachment	6 (7.4)	17 (18.3)	.043	13.6	14.0	.94
Left atrial vent	36 (44.4)			45.7	_	
Concomitant CABG	1 (1.2)	3 (3.2)	.38	3.7	2.2	.67

IPTW, Inverse probability of treatment weighting; DHCA, deep hypothermic circulatory arrest; AC, arch clamping; SD, standard deviation; GFR, glomerular filtration rate; SIA, segmental intercostal artery; CABG, coronary artery bypass grafting.

TABLE 2. Early outcomes (unadjusted)

Variables	DHCA (N = 81), n (%)	AC (N = 93), n (%)	P valu
30-d or in-hospital mortality	9 (11.1)	8 (8.6)	.58
Major complication	31 (38.3)	29 (31.2)	.33
Bleeding problem (reexploration + massive bleeding)	11 (13.6)	14 (15.1)	.78
Bleeding reexploration	7 (8.6)	10 (10.8)	.64
Requirement for new dialysis	13 (16.0)	17 (18.3)	.70
Low cardiac output syndrome*	10 (12.3)	5 (5.4)	.11
CVA/TIA	8 (9.9)	8 (8.6)	.77
Paraplegia	1 (1.2)	9 (9.7)	.017
Wound revision	6 (7.4)	11 (11.8)	.33
Pneumonia	14 (17.3)	11 (11.8)	.31
Visceral, leg ischemia	4 (4.9)	1 (1.1)	.13
Multiorgan failure	4 (4.9)	6 (6.5)	.67
Ventilation duration, h (interquartile range)	52 (12-86)	24 (23-94)	.51
Prolonged ventilation (>24 h)	60 (74.1)	46 (49.5)	.001
Prolonged ventilation (>48 h)	41 (59.4)	28 (40.6)	.006
Intensive care unit stay, d (interquartile range)	7 (3-9)	5 (5-10)	.55
Hospital stay, d (interquartile range)	29 (15-34)	22 (19-48)	.75

DHCA, Deep hypothermic circulatory arrest; AC, arch clamping; CVA, cerebrovascular accident; TIA, transient ischemic attack. *Requiring mechanical support (intra-aortic balloon pulsation or venoarterial extracorporeal membrane oxygenation).

The adjusted ORs of adverse outcomes in the DHCA versus AC groups are summarized in Figure 2. After adjustment, there were no significant differences in the death rate and the major complication rate including death (P = .80 and P = .56, respectively). However, compared with the AC group, the DHCA group showed a tendency for a lower risk of paraplegia (OR, 0.15; 95% CI, 0.02-1.06; P = .057) and a significantly increased risk of prolonged mechanical ventilation (OR, 2.60; 95% CI, 1.39-4.87; P = .003).

DISCUSSION

In the open repair of DTA/TAAA, there have been advances in various adjunct procedures to protect spinal cord ischemia and visceral organ dysfunction, resulting in decreased rates of surgery-related morbidity and mortality. Contemporary data from several experienced large-volume aortic centers have shown superior outcomes (mortality rate around 7%-9% and paraplegia rate less than 6%).^{7,9} However, a recent meta-analysis on open surgical repair

Adverse Outcomes		Adjusted OR	95% CI	p value
Death		1.14	0.41-3.18	0.80
Permanent neurologic injury		0.95	0.38-2.36	0.92
Stroke		1.22	0.45-3.36	0.70
Paraplegia		0.15	0.02-1.06	0.057
LCOS *		2.05	0.66-6.36	0.21
Dialysis	_	0.75	0.33-1.73	0.50
Visceral or limb malperfusion		4.57	0.62-33.98	0.14
Multi-organ failure		0.80	0.22-2.87	0.73
Pneumonia	_	1.41	0.57-3.46	0.46
Bleeding problem		0.77	0.31-1.89	0.56
Wound problems requiring revision		0.71	0.24-2.07	0.53
Death + neurologic injury + LCOS *		1.60	0.69-3.70	0.27
Death + major complication		1.22	0.64-2.32	0.56
Prolonged ventilation (> 24hr)		2.60	1.39-4.87	0.003
0.010.1	110)		
favors D	HCA favors	ACÍ		

FIGURE 2. Forrest plot for adjusted odds ratios of adverse outcomes of deep hypothermic circulatory arrest compared with arch clamping. *Requiring mechanical support (intra-aortic balloon pulsation or venoarterial extracorporeal membrane oxygenation). *OR*, Odds ratio; *CI*, confidence interval; *LCOS*, low cardiac output syndrome; *DHCA*, deep hypothermic circulatory arrest; *AC*, arch clamping.

of TAAA, which included 28 reports published between 2000 and 2010, demonstrated that despite a dramatic improvement in the surgical mortality and morbidity, the 30-day mortality rate ranged from 4.2% to 18%, the rate of spinal cord ischemia ranged from 2% to 28% (mean 7.5%), and the rate of renal injury was also high, up to 40%.¹⁶ These findings imply that open repair of DTA/TAAA is still a challenging procedure for many cardiovascular surgeons.

Furthermore, DTA/TAAA involving the distal arch is even more challenging because extensive manipulation of the aortic arch for crossclamping is required, which may increase the risk of embolic stroke. Kay and colleagues¹ reported on a simple clamp-and-sew technique without adjuncts for distal protection in 32 patients, resulting in a 6% mortality rate with no strokes despite AC, but the rate of paraplegia was 9.4%. Girardi and colleagues¹¹ investigated the outcomes of AC during TAAA surgery and compared the results between patients with and without distal arch involvement. They concluded that AC did not increase the risk of mortality or major neurologic complications. By contrast, Okita and colleagues¹² reported that AC was the strongest risk factor for stroke with arteriosclerotic aneurysms of the aortic arch. The only viable alternative to AC for proximal control in this type of DTA/TAAA surgery is DHCA. Several retrospective studies have shown acceptable early outcomes of DHCA in patients undergoing open DTA/TAAA repair.^{17,18} DHCA may provide superior protection to the spinal cord and visceral organs during prolonged procedures than any other form of partial bypass under moderate hypothermia.^{19,20} However, the routine use of DHCA for DTA/TAAA repairs is a debatable issue because of concerns about cerebral ischemia and myocardial protection, as well as hypothermic tissue damage, and systemic and pulmonary edema.²¹ In addition, the longer CPB time required to achieve DHCA, and the impairment of the coagulation cascade and platelet function induced by profound hypothermia may increase the risk of serious surgical bleeding.²²

No previous studies to date have compared DHCA and AC for DTA/TAAA involving the distal arch. Therefore, this study is unique in comparing the outcomes of DHCA with the AC technique in this setting and has demonstrated similar overall clinical outcomes between the 2 patient groups. Although an increased risk of prolonged mechanical ventilation was associated with DHCA, it showed a decreased tendency for the risk of spinal cord injury.

Higher Rate of Paraplegia in the AC Group

The rate of paraplegia was higher in the AC group in this study (Table 2). Postoperative paraplegia occurred in only 1 patient in the DHCA group; it occurred in 9 patients in the AC group, 7 of whom (7 of 9; 77.8%) underwent Crawford extent type I or II surgery. CSF drainage was used in these 7

patients (extent I or II; 100%), and in 1 of the 2 patients with DTA only (1 of 2; 50%). The results of our study support the collateral network concept described by Griepp and colleagues¹³; occlusion of the collateral flow from the LSCA or hypogastric artery may influence spinal cord ischemia,¹ and mild or moderate hypothermia alone may not afford sufficient spinal cord protection during the clamping period. This hypothesis is also supported by data from the European Registry on Endovascular Aortic Repair Complications,²³ which showed that extensive coverage of intercostal arteries alone was not associated with spinal cord injury, but simultaneous closure of the collateral vascular territories was highly related to the development of spinal cord injury. DHCA might be more advantageous in extensive procedures where the risk of spinal cord ischemia can be significant. The protective effect of homogeneous hypothermia on the spinal cord from aortic clamping-induced ischemia has been demonstrated in both experimental and clinical studies.^{3,19}

High Rate of Strokes in Both Groups

The rate of strokes was high not only in the AC group but also in the DHCA group (Table 2). This may have been caused by factors other than the type of CPB strategy or clamping of the arch, such as retrograde perfusion from the femoral artery or the presence of increased embolic burden in the DTA or the arch itself.²⁴ For example, if the embolic source is at the arch level, not only AC but the retrograde perfusion itself could be problematic. In the aortic condition where the embolic source is mainly located in the proximal DTA, open anastomosis under DHCA alone does not reduce the stroke risk much because the unprotected emboli can be dislodged into the arch vessels. For this clinical presentation, AC may be more protective against embolic stroke. In this regard, we reviewed the preoperative computed tomography (CT) images of the 16 patients who had postoperative stroke (Table 3). Twelve of these patients were found to have a preoperative embolic source in the aorta that was definitely visible on the CT images. Moreover, in 6 of the patients who underwent DHCA (6 of 7, 85.7%), embolic sources were located at the isthmus area.

Prolonged Mechanical Ventilation in the DHCA Groups

Another significant finding of the present study is that the need for prolonged mechanical ventilation was more frequent in the AC group (OR, 2.60; 95% CI, 1.39-4.87; P = .003; Figure 2). Pulmonary complications are still the most common postoperative complications of DTA/TAAA repair, reported to be as high as 40%.¹⁶ Obviously, the DHCA technique requires a longer operative time to increase and decrease the body temperature, as a result of

TABLE 3. The relationship between the proximal control strategy and the presence or location of an embolic burden among the patients who had a postoperative stroke

Patient	Proximal control	Presence of an embolic burden	Location of the embolic burden
1	AC	+	Arch
2	AC	+	Arch
3	AC	+	Arch
4	AC	+	Isthmus
5	AC	+	Isthmus
6	DHCA	+	Isthmus
7	DHCA	+	Isthmus
8	DHCA	+	Isthmus
9	DHCA	+	Isthmus
10	DHCA	+	Isthmus
11	DHCA	+	Isthmus
12	DHCA	+	Arch
13	AC	_	_
14	AC	_	_
15	AC	_	_
16	AC	_	_

AC, Arch clamping; DHCA, deep hypothermic circulatory arrest.

which the risks of bleeding and pulmonary edema are also increased.

High Rate of Major Complications in Both Groups

The rate of major complications such as acute renal failure and low cardiac output was extraordinarily high in both groups even compared with the rates in the recent metaanalysis (Table 2).¹⁶ Although it is difficult to attribute the high rates of renal complications and low cardiac output to certain causes, we assume that those complications are closely related to the extensive nature of surgery involving the arch as well as perioperative bleeding complications related to such extensive surgery.

Furthermore, the heart under DHCA without cardioplegia might be more susceptible to myocardial damage. Myocardial distention injury may further critically compromise the outcomes for this particular type of surgery. However, an LA vent was used in only 44.4% of the patients who underwent DHCA in our study, and this we believe implies that the hypothermic technique was not applied in ideal fashion in many of the cases. In addition, a potentially suboptimal deairing procedure on the left ventricle (LV) without an LV vent could also have contributed to ischemic insult to the myocardium. Taking all these considerations into account, we have changed our strategy to assertively insert an LV vent (through the LV apex) when conducting DHCA.

In conclusion, in the surgical repair of DTA/TAAA involving the distal arch, either the DHCA or the AC technique may be feasible with similar results. Therefore, the CPB strategy should be based on the individual patient's condition (ie, aortic anatomy, embolic burden) and on the surgeon's preference.

Limitations

This study is subject to the limitations inherent in observational and retrospective data. The nonrandomized design may have affected the results because of unmeasured confounders, procedure bias, or detection bias, despite the use of rigorous statistical adjustment. This study represents the experience of a single, large, tertiary referral center, and might not be generalizable to other centers.

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