Aortic balloon occlusion technique versus moderate hypothermic circulatory arrest with antegrade cerebral perfusion in total arch replacement and frozen elephant trunk for acute type A aortic dissection

Yanxiang Liu, MD, Yi Shi, MD, Hongwei Guo, MD, Cuntao Yu, MD, Xiangyang Qian, MD,
Wei Wang, MD, and Xiaogang Sun, MD

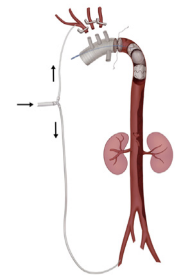
ABSTRACT

Background: Moderate hypothermic circulatory arrest (MHCA) with antegrade cerebral perfusion (ACP) is safe and efficient in total arch replacement (TAR) and frozen elephant trunk (FET) for acute type A aortic dissection (ATAAD). Complications related to hypothermia and ischemia are inevitable, however. The aortic balloon occlusion (ABO) technique is performed to elevate the lowest nasopharyngeal temperature to 28°C and shorten the circulatory arrest time. In this study, we aimed to evaluate the efficacy of this new technique.

Methods: We reviewed the clinical data of patients with ATAAD who underwent TAR and FET, including 79 who underwent ABO and 109 who underwent MHCA/ACP.

Results: Circulatory arrest time was significantly lower in the ABO group compared with the MHCA/ACP group (mean, 4.8 ± 1.2 minutes vs 18.4 ± 3.1 minutes; $P < .001$). The composite endpoint was comparable in the 2 groups (11.4% for ABO vs 13.8% for MHCA/ACP; $P = .631$). Fewer patients in the ABO group developed high-grade acute kidney injury (AKI) according to a modified RIFLE criterion (22.8% vs 36.7%; $P = .041$), and the rate of hepatic dysfunction was lower in the ABO group (11.4% vs 28.4%; $P = .005$). Multivariable logistic analysis showed that the ABO technique is protective against duration of ventilation >24 hours (odds ratio [OR], 0.455; 95% confidence interval [CI], 0.234-0.887; $P = .021$), hepatic dysfunction (OR, 0.218; 95% CI, 0.084-0.561; $P = .002$), and grade II-III AKI (OR, 0.432; 95% CI, 0.204-0.915; $P = .028$).

Conclusions: The ABO technique significantly shortens the circulatory arrest time in TAR and FET. Available clinical data suggest that it has a certain protective effect on the liver and kidney. Future large-sample studies are warranted to thoroughly evaluate this new technique. (J Thorac Cardiovasc Surg 2021;161:25-33)



When the balloon occludes the descending aorta, the perfusion of the lower body is resumed.

Central Message

The aortic balloon occlusion technique in total arch replacement and frozen elephant trunk shortens circulatory arrest time and has a certain protective effect on the liver and kidney.

Perspective

Although the sample size of this study is relatively small, a trend toward a protective effect of the aortic balloon occlusion (ABO) technique is seen. We believe that ABO is a promising technique to change the current status of aortic arch surgery, allowing total arch replacement under mild hypothermia safely and easily. This technique will also promote innovation in medical devices.

See Commentary on pages 34.

Given the increasingly frequent reports of excellent outcomes of the total aortic arch replacement (TAR) with frozen elephant trunk (FET) technique,[1-3] it is now well recognized as a recommended treatment for acute type A aortic dissection (ATAAD).[4,5] This surgical technique was

Scanning this QR code will take you to the article title page to access supplementary information.

From the Department of Cardiovascular Surgery, State Key Laboratory of Cardiovascular Disease, Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China.

This work was supported by the Beijing Municipal Science and Technology Commission (Z181100001718197).

Received for publication March 27, 2019; revisions received Aug 8, 2019; accepted for publication Aug 12, 2019; available ahead of print Oct 4, 2019.

Address for reprints: Xiaogang Sun, MD or Wei Wang, MD, Department of Cardiovascular Surgery, Fuwai Hospital, No. 167 North Lishi Rd, Xicheng District, Beijing 100037, China (E-mail: xiaogangsunl@163.com or weiwanglyx@163.com).

0022-5223/$36.00

https://doi.org/10.1016/j.jtcvs.2019.08.074

Abbreviations and Acronyms

ABO = aortic balloon occlusion
ACP = antegrade cerebral perfusion
AKI = acute kidney injury
ATAAD = acute type A aortic dissection
CPB = cardiopulmonary bypass
FET = frozen elephant trunk
GFR = glomerular filtration rate
MHCA = moderate hypothermic circulatory arrest
sCr = serum creatinine
TAR = total arch replacement

initially developed with a circulatory management strategy of deep hypothermic circulatory arrest. More recently, the use of selective cerebral perfusion has allowed for aortic arch repair with moderate hypothermic circulatory arrest (MHCA).[6-8] However, there is a concern that this approach may carry an increased risk of ischemic organ injury.

The rationale behind the aortic balloon occlusion (ABO) technique is that the lower body can be perfused through the femoral artery when the descending aorta is blocked by the balloon, thereby shortening circulatory arrest time to approximately 5 minutes. With the visceral organs well perfused, the desired temperature is elevated to 28°C. TAR with FET is performed under moderate hypothermia (nasopharyngeal temperature 28°C) and transient circulatory arrest. Here, we present our initial and largest series of patients treated with the ABO technique and evaluate its efficacy in the treatment of ATAAD.

PATIENTS AND METHODS

Patients

A total of 188 patients with ATAAD involving the arch and descending aorta who underwent TAR with FET between August 2017 and January 2019 were enrolled in this study, including 79 in the ABO group and 109 in the MHCA with antegrade cerebral perfusion (MHCA/ACP) group. The ABO technique was approved by the Ethics Committees of Fuwai Hospital in Beijing. Because this was a retrospective study, the requirement for informed consent was waived. Patient characteristics are summarized in Table 1.

Myocardial malperfusion was defined as acute myocardial infarction with ST-segment elevation, abnormal ventricular wall motion on echocardiography, and significantly increased value of serum cardiac troponin I. Cerebral and gastrointestinal malperfusion were defined as an alteration in mental status and symptoms of abdominal pain or distention, respectively. Limb malperfusion was defined as the absence of pulse with limb compromise. Kidney and liver function was assessed by serum creatinine (sCr) and transaminase levels measured closest to the start of surgery.

Surgical Procedure

The detailed surgical procedure for the ABO technique have been described previously.[9] In brief, ABO device consists of 2 parts, an aortic balloon catheter (Coda Balloon Catheter, Cook, Bloomington, Ind) and a sheath (W. L. Gore & Associates, Flagstaff, Ariz) (Figure 1, *A*). When in use, the sheath is sheathed on the catheter (Figure 1, *B*). Before surgery, the device is passed through the trimmed 4-branched prosthetic graft (Terumo, Vascutek Limited, Renfrewshire, UK) to facilitate distal anastomosis of the arch (Figure 1, *C*). Cardiopulmonary bypass (CPB) is instituted through the right axillary and femoral arteries, and the right axillary artery is used for selective cerebral perfusion. During the cooling phase, aortic root procedures are performed as indicated. When the nasopharyngeal temperature reaches 28°C, ACP is started at a flow rate of 5.0 to 8.0 mL/kg/min. The arch is transected between the left common carotid and left subclavian arteries, to prevent recurrent laryngeal nerve injury. A stented graft (Cronus; MicroPort Scientific, Shanghai, China) is inserted into the true lumen of the descending aorta. The aortic balloon with the sheath is deployed into the metal part of the stented graft. Then the balloon is filled with saline and pressed by the sheath to prevent displacement (Figure 1, *D*). Once the balloon is fixed, perfusion of the lower body is resumed through the femoral artery, and the CPB flow is gradually returned to one-half the full rate (Figure 2). After the descending aorta is anastomosed to the 4-branched graft, the balloon and sheath are removed, and the proximal end of the tetrafurcate graft was clamped. After the left common carotid artery anastomosis was finished, CPB flow was gradually returned to normal and rewarming was initiated. Finally, other branches of the aortic arch and ascending aorta were reconstructed during the rewarming phase (Video 1).

The MHCA/ACP technique has been described previously as well.[10] The procedure differs from the ABO technique in the following ways. First, the right axillary artery is cannulated for CPB and selective cerebral perfusion, whereas the femoral artery is not cannulated. Second, ACP is instituted when the nasopharyngeal temperature reaches 24°C. Third, the anastomosis of the 4-branched graft and descending aorta is performed with circulatory arrest of the lower body, compared with the simultaneous perfusion of the brain and lower body through a bifurcated arterial line in the ABO technique. This is the fundamental difference between the 2 procedures. Finally, when the distal anastomosis is completed, perfusion of the lower body is resumed through the perfusion limb of the tetrafurcate graft. The other steps are the same as in the ABO technique.

Study Endpoints and Statistical Analysis

The primary endpoint was a composite of adverse events that included 30-day mortality, stroke, paraplegia, renal failure necessitating hemodialysis at discharge, and cardiac dysfunction requiring intra-aortic balloon pump assistance. Paraplegia was defined as muscle strength of lower limb $\leq$grade 3 (able to resist gravity but not resistance).

Secondary endpoints included hepatic dysfunction and acute kidney injury (AKI). The peak value of aspartate aminotransferase or alanine aminotransferase within 48 hours after surgery was collected; hepatic dysfunction was defined as this peak value exceeding 100 IU/L. AKI was diagnosed and categorized according to classifications of clinical endpoints of the renal system from the International Aortic Arch Surgery Study Group, with slight modifications[11] and when the postoperative sCr increased by >1.5 times over baseline values or glomerular filtration rate (GFR) decreased by >25% in the first 7 days. Urine output was not taken into consideration because of its inaccuracy when collected retrospectively. Due to the absence of follow-up data, the outcomes of renal function after discharge were unknown. AKI grade IV in the classification was omitted; temporary hemodialysis during hospitalization and hemodialysis at discharge were considered grade III. AKI was staged for severity according to the criteria presented in Table 2.

Preoperative GFR and lowest GFR in the first 7 days after surgery were calculated using the Modification of Diet in Renal Disease equation: estimated GFR = 186 × (plasma creatinine level [in mg/dL]$^{-1.154}$ × (age [in years])$^{-0.203}$. For women, the product of this equation was multiplied by a correction factor of 0.742.[12]

TABLE 1. Preoperative characteristics

Variables	Total cohort (n = 188)	ABO (n = 79)	MHCA/ACP (n = 109)	*P* value
Demographics				
Age, y, mean ± SD	46.9 ± 10.7	48.5 ± 12.7	45.8 ± 8.9	.104
Female sex, n (%)	42 (22.3)	18 (22.8)	24 (22.0)	.901
BMI, kg/m^2, mean ± SD	26.5 ± 4.0	26.5 ± 3.6	26.6 ± 4.3	.791
Medical history, n (%)				
Hypertension	165 (87.8)	70 (88.6)	95 (87.2)	.764
Coronary artery disease	30 (16.0)	12 (15.2)	18 (16.5)	.807
Diabetes	9 (4.8)	5 (6.3)	4 (3.7)	.619
Chronic renal dysfunction	2 (1.1)	0 (0.0)	2 (1.8)	.510
Marfan syndrome	10 (5.1)	4 (5.1)	6 (5.5)	1.000
COPD	2 (1.1)	2 (2.5)	0 (0.0)	.175
Cerebrovascular accident	12 (6.4)	6 (7.6)	6 (5.5)	.563
Myocardial infarction	2 (1.1)	1 (1.3)	1 (0.9)	1.000
NYHA grade ≥III	3 (1.6)	2 (2.5)	1 (0.9)	.778
Malperfusion syndromes, n (%)				
Myocardial	5 (2.7)	3 (3.8)	2 (1.8)	.714
Cerebral	6 (3.2)	2 (2.5)	4 (3.7)	.986
Gastrointestinal	4 (2.1)	2 (2.5)	2 (1.8)	1.000
Lower extremity	10 (5.3)	3 (3.8)	7 (6.4)	.644
Ejection fraction, %, median (IQR)	60.0 (4.0)	60.0 (4.0)	60.0 (3.5)	.556
Median or massive AI, n (%)	57 (30.3)	25 (31.6)	32 (29.4)	.736
sCr, μmol/L, median (IQR)	85.7 (43.4)	87.8 (37.2)	84.9 (52.7)	.940
sCr >200 μmol/L, n (%)	7 (3.7)	1 (1.3)	6 (5.5)	.261
ALT, IU/L, median (IQR)	21 (19.0)	21.0 (17.0)	20.0 (19.5)	.744
AST, IU/L, median (IQR)	21 (14.0)	21.0 (11.0)	21.0 (15.5)	.874
ALT or AST >100 IU/L, n (%)	8 (4.3)	4 (5.1)	4 (3.7)	.919

ABO, Aortic balloon occlusion; *MHCA/ACP*, moderate hypothermic circulatory arrest/antegrade cerebral perfusion; *SD*, standard deviation; *BMI*, body mass index; *COPD*, chronic obstructive pulmonary disease; *NYHA*, New York Heart Association; *IQR*, interquartile range; *AI*, aortic insufficiency; *sCr*, serum creatinine; *ALT*, alanine aminotransferase; *AST*, aspartate aminotransferase.

Ventilation time exceeding 24 hours was also considered an endpoint based on the hypothesized strong association between postoperative awake time and ventilator support time. Awake time was considered to reflect cerebral function after surgery.

Categorical variables were compared using Pearson's χ^2 test or Fisher's exact test. Continuous variables were expressed as appropriate and analyzed with the Student *t* test or Mann-Whitney *U* test. Multivariable logistic regression analysis was applied to analyze whether the ABO

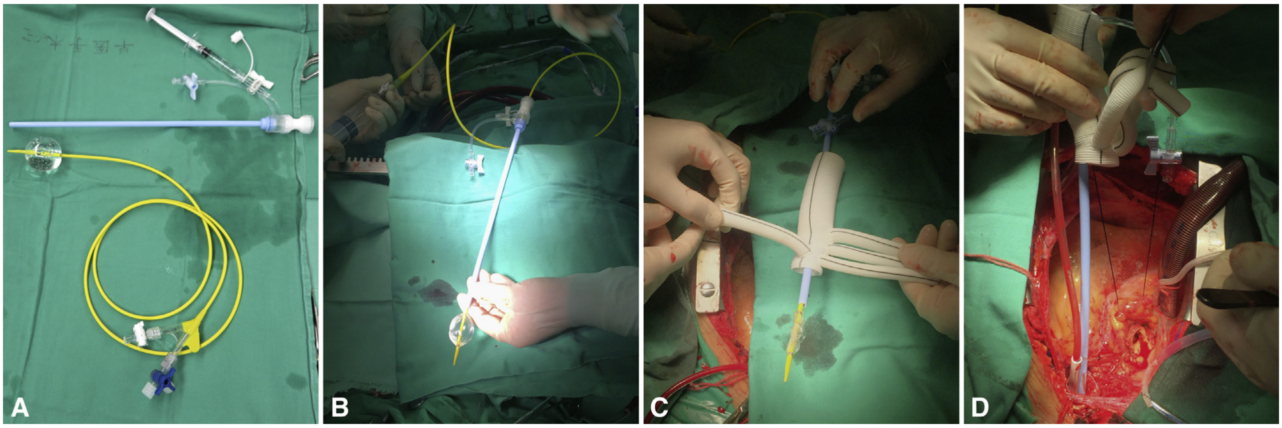


FIGURE 1. A, Components of the aortic balloon occlusion device. An aortic balloon (*yellow*; Coda Balloon Catheter, Cook, Bloomington, Ind) and a sheath (*blue*, W.L. Gore & Associates, Flagstaff, Ariz). B, Device assembly. The sheath is sheathed on the balloon catheter, and the balloon is tested. C, To facilitate the distal arch anastomosis, the aortic balloon occlusion device is passed through the trimmed 4-branched prosthetic graft (Terumo; Vascutek, Renfrewshire, UK). D, The aortic balloon is placed into the stented graft, blocking the flow from femoral artery cannulation. The sheath is used to press the balloon to resist the pressure of blood flow.

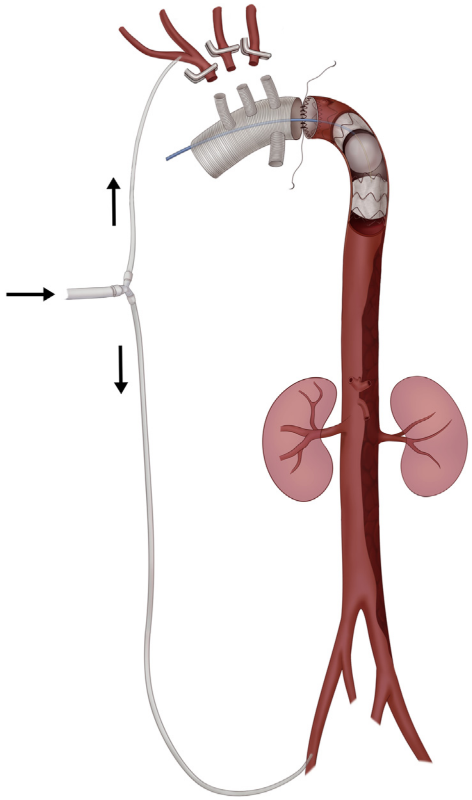


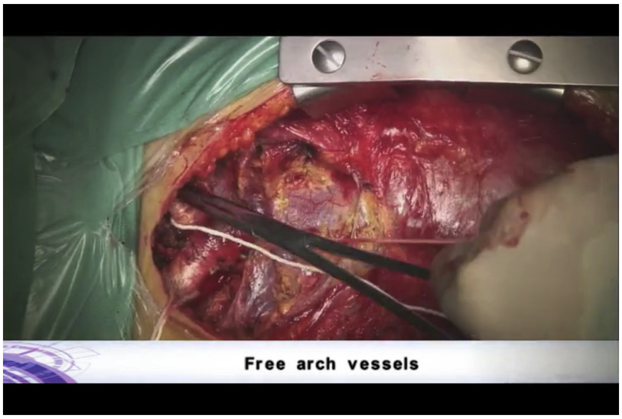
FIGURE 2. The aortic balloon occlusion technique for total arch replacement and frozen elephant trunk. The stented graft is inserted into the descending aorta with selective cerebral perfusion. Then an aortic balloon is placed into the stented graft, positioned at its metal part and pressed by a sheath to avoid displacement. Subsequently, the femoral artery cannulation is opened, and the distal arch anastomosis is performed with simultaneous perfusion of the lower body and brain through a bifurcated arterial line. Therefore, circulatory arrest time is significantly shortened.

technique is a protective factor for the composite of adverse events, stroke, hepatic dysfunction, and ventilation time >24 hours. The effect of the ABO technique in patients with AKI grade II-III (the sum of grades II and III) was also analyzed by multivariable regression analysis owing to the significant difference in the incidence of AKI grade II and III compared with AKI grades I, II, and III. Clinically important variables with a *P* value of <.1 in single-factor analysis were included in the multivariable logistic regression analysis. Of note, circulatory arrest time was removed from the model, to avoid collinearity in multivariable regression analysis. All the statistical tests were 2-sided, and a *P* value of ≤.05 was considered to indicate statistical significance. All statistical analyses were done using SPSS version 25 (IBM, Armonk, NY).

RESULTS

Baseline Characteristics

The ABO and MHCA/ACP groups were well matched in baseline characteristics. The incidences of malperfusion syndrome of the heart, brain, gastrointestinal system, and lower limbs were comparable in the 2 groups, and there were no significant differences in preoperative sCr, alanine aminotransferase, and aspartate aminotransferase levels irrespective of whether the variables are described as continuous or categorical (Table 1). These variables are of concern, because they could be confounding factors in assessment of the efficacy of the ABO technique for organ protection.



VIDEO 1. Aortic balloon occlusion technique in total arch replacement and frozen elephant trunk. Before surgery, the 4-branched prosthetic graft was trimmed, and the aortic balloon in a sheath was passed through the branched graft to facilitate distal anastomosis of the aortic arch. The surgery was performed through a standard median sternotomy under cardiopulmonary bypass (CPB) and selective cerebral perfusion through the right axillary artery. The femoral artery was also cannulated for perfusion to the lower body after the aortic balloon occluded the descending aorta. During the cooling phase, aortic root procedures were performed if indicated. When the nasopharyngeal temperature reached 28°C, antegrade cerebral perfusion was instituted. After the transverse arch was transected, a stented graft was inserted into the true lumen of the descending aorta, then the aortic balloon with the sheath was placed into the metal part of the stented graft. Once the balloon was fixed, perfusion of the lower body was resumed through the femoral artery with CPB flow gradually returned to one-half of the full rate. Once the distal arch anastomosis was completed, the balloon and sheath were removed, and the proximal end of the tetrafurcate graft was clamped. The left common carotid artery was reconstructed first, after which CPB flow was returned to normal and rewarming was begun; this was followed by the ascending aorta and then the left subclavian and innominate arteries. Video available at: https://www.jtcvs.org/article/S0022-5223(19)31850-1/fulltext.

Intraoperative Data

Table 3 presents surgical strategies and perioperative data for the ABO and MHCA/ACP groups. Rates of use of the Bentall operation, Valsalva sinus reconstruction, coronary artery bypass grafting, extra-anatomic bypass, and other (eg, Wheats, David) procedures were not significantly different in the 2 groups.

The ABO group demonstrated longer CPB time (mean, 193.5 ± 51.3 minutes vs 180.5 ± 57.9 minutes: *P* = .033) and cross-clamp time (mean, 126.6 ± 33.5 minutes vs 116.6 ± 40.9 minutes; *P* = .017). Circulatory arrest time was significantly decreased in the ABO group (mean,

TABLE 2. Classifications of clinical endpoints of the renal system

Renal system	Grade 0	Grade I	Grade II	Grade III
Renal dysfunction (modified RIFLE classification)	No AKI	Serum creatinine increased by >1.5 times the baseline values; GFR decreased by >25%	Serum creatinine increased by 2-3 times the baseline value; GFR decreased by >50%	Serum creatinine increased by >3 times the baseline value; GFR decreased by >75%, necessitating temporary hemodialysis during hospitalization or hemodialysis at discharge

AKI, Acute kidney injury; *GFR*, glomerular filtration rate.

4.8 ± 1.2 minutes vs 18.4 ± 3.1 minutes; *P* < .001). There were also significant differences in nasopharyngeal temperature (28.1 ± 0.6°C for ABO vs 24.6 ± 1.0°C for MHCA/ACP; *P* <. 001) and bladder temperature (29.5 ± 0.9°C for ABO vs 27.1 ± 1.3°C for MHCA/ACP; *P* < .001) between the 2 groups.

Primary and Second Endpoints and Other Morbidities

As shown in Table 4, the rate of composite of adverse events was 11.4% for the ABO group and 13.8% for the MHCA/ACP group (*P* = .631). There also were no significant differences between the ABO and MHCP/ABP groups in 30-day mortality (1.3% vs 3.7%; *P* = .581), stroke (3.8% vs 2.8%; *P* = 1.000), paraplegia (1.3% vs 4.6%; *P* = .391), continuous renal replacement therapy (7.6% vs 10.1%; *P* = .556), intra-aortic balloon pump (0% vs 1.8%; *P* = .624), and reintubation (6.3% vs 1.8%; *P* = .224) in each group.

The mean duration of postoperative mechanical ventilation was shorter in the ABO group compared with the MHCA/ACP group (31.4 ± 32.3 hours vs 45.7 ± 43.6 hours; *P* = .017). There was a trend toward less need for ventilator support for >24 hours in the ABO group (38% vs 51.4%; *P* = .069). No significant between-group differences were observed in the intensive care unit time and in-hospital time. There was a significant between-group difference in the rate of postoperative hepatic dysfunction (11.4% for ABO vs 28.4% for MHCA/ACP; *P* = .005).

No significant between-group difference was observed in the distribution of stages of AKI (*P* = .231), but there was a trend toward higher rates of AKI and AKI grade III in the MHCA/ACP group. In addition, the proportion of AKI grade II-III (the sum of the 2 grades) was significantly higher in the MHCA/ACP group (36.7% vs 22.8%; *P* = .041) (Figure 3, *A*). Postoperative GFR was higher in the ABO group (55.9 [interquartile range (IQR), 33.5] vs 43.9 [IQR, 34.5]; *P* = .024) (Figure 3, *B*).

Multivariable Logistic Regression Analysis

ABO technique was not associated with composite of adverse events and stroke in the univariate logistic regression model (*P* > .1) and was not included in the multivariable regression analysis. Multivariable regression analysis identified coronary heart disease and lower extremity malperfusion as independent predictors of composite adverse events. Stroke was predicted by longer cross-clamp time (Tables 5 and 6).

TABLE 3. Surgical strategies and perioperative data

Variable	Total cohort (n = 188)	ABO (n = 79)	MHCA/ACP (n = 109)	*P* value
TAR with FET, n (%)	188 (100.0)	79 (100.0)	109 (100.0)	1.000
Combined surgery, n (%)				
Bentall procedure	44 (23.4)	16 (20.3)	28 (25.7)	.385
Valvasa sinus reconstruction	47 (25.0)	19 (24.1)	28 (25.7)	.798
CABG	33 (17.6)	13 (16.5)	20 (18.3)	.736
Extra-anatomic bypass	8 (4.3)	2 (2.5)	6 (5.5)	.528
Other (Wheats, David)	8 (4.3)	4 (3.7)	4 (5.1)	.919
CPB time, min, mean ± SD	186.0 ± 55.5	193.5 ± 51.3	180.5 ± 57.9	.033
Cross-clamp time, min, mean ± SD	120.8 ± 38.2	126.6 ± 33.5	116.6 ± 40.9	.017
Circulatory arrest time, min, mean ± SD	12.7 ± 7.2	4.8 ± 1.2	18.4 ± 3.1	<.001
Lowest nasopharyngeal temperature, °C, mean ± SD	26.1 ± 1.9	28.1 ± 0.6	24.6 ± 1.0	<.001
Lowest bladder temperature, °C, mean ± SD	28.1 ± 1.7	29.5 ± 0.9	27.1 ± 1.3	<.001

ABO, Aortic balloon occlusion; *MHCA/ACP*, moderate hypothermic circulatory arrest; *TAR*, total arch replacement; *FET*, frozen elephant trunk; *CABG*, coronary artery bypass grafting; *CPB*, cardiopulmonary bypass; *SD*, standard deviation.

TABLE 4. 30-day mortality and morbidity

Variables	Total cohort (n = 188)	ABO (n = 79)	MHCA/ACP (n = 109)	P value
Ventilation time, h, mean ± SD	39.7 ± 39.8	31.4 ± 32.3	45.7 ± 43.6	.017
Ventilation time >24 h, n (%)	86 (45.7)	30 (38.0)	56 (51.4)	.069
ICU length of stay, h, mean ± SD	122.1 ± 96.8	121.3 ± 99.9	122.8 ± 95.0	.814
Hospital length of stay, d, mean ± SD	12.7 ± 4.7	12.3 ± 5.0	12.9 ± 4.5	.139
Composite adverse events, n (%)	24 (12.8)	9 (11.4)	15 (13.8)	.631
30-d mortality, n (%)	5 (2.7)	1 (1.3)	4 (3.7)	.581
Stroke, n (%)	6 (3.2)	3 (3.8)	3 (2.8)	1.000
Paraplegia, n (%)	6 (3.2)	1 (1.3)	5 (4.6)	.391
CRRT, n (%)	17 (9.0)	6 (7.6)	11 (10.1)	.556
CRRT at discharge, n (%)	14 (7.4)	5 (6.3)	9 (8.3)	.619
IABP, n (%)	2 (1.11)	0 (0.0)	2 (1.8)	.510
Reintubation, n (%)	7 (3.7)	5 (6.3)	2 (1.8)	.224
Hepatic dysfunction, n (%)	40 (21.3)	9 (11.4)	31 (28.4)	.005
Acute kidney injury, n (%)				
Grade 0	48 (25.5)	23 (29.1)	25 (22.9)	.231
Grade I	82 (43.6)	38 (48.1)	44 (40.4)	
Grade II	31 (16.5)	9 (11.4)	22 (20.2)	
Grade III	27 (14.4)	9 (11.4)	18 (16.5)	

ABO, Aortic balloon occlusion; *MHCA/ACP*, moderate hypothermic circulatory arrest; *ICU*, intensive care unit; *CRRT*, continuous renal replacement therapy, includes temporary CRRT and CRRT at discharge; *IABP*, intra-aortic balloon pump.

For ventilation time >24 hours, hepatic dysfunction and AKI grade II-III, the ABO technique had a P value of <.1 in univariate logistic regression analysis, and was included in the multivariable regression analysis. Multivariable logistic analysis showed that the ABO group had a lower risk of ventilation time >24 hours (odds ratio [OR], 0.455; 95% confidence interval [CI], 0.234-0.887; P = .021), hepatic dysfunction (OR,

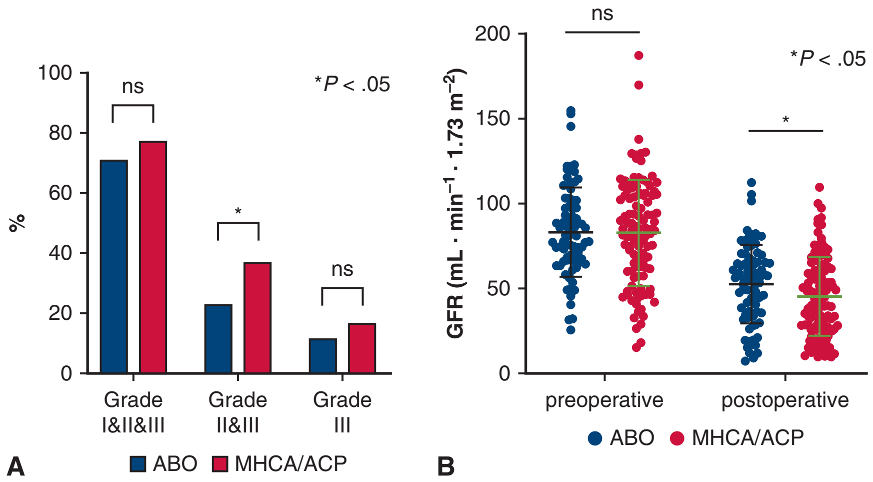


FIGURE 3. A, Postoperative stages of AKI. The percentage of AKI (grade I, II, and III) was comparable in the 2 groups (70.9% for ABO vs 77.1% for MHCA/ACP; $P = .338$). More patients in MHCA/ACP group developed AKI of grade II-III (36.7% vs 22.8%; $P = .041$). No significant difference in the occurrence of AKI grade III (11.4% for ABO vs 16.5% for MHCA/ACP; $P = .323$). B, Preoperative and postoperative GFR. There was no significant between-group difference in the preoperative GFR (81.0 [IQR, 32.3] for ABO vs 84.1 [IQR, 45.1] for MHCA/ACP; $P = .947$). Patients in the ABO group had a higher median postoperative GFR (55.9 [IQR, 33.5] vs 43.9 [IQR, 34.5]; $P = .024$). The grade of AKI was defined by a modified RIFLE (risk, injury, failure, loss, and end-stage kidney disease) classification. *ABO*, Aortic balloon occlusion; *MHCA*, moderate hypothermic circulatory arrest; *ACP*, antegrade cerebral perfusion; *GFR*, glomerular filtration rate.

TABLE 5. Univariate logistic analysis for risk factors associated with composite adverse events, stroke, ventilation time >24 h, hepatic dysfunction, and AKI of grade II-III

Factors	*P* value				
	Composite adverse events	Stroke	Ventilation time >24 h	Hepatic dysfunction	AKI grade II-III
ABO	.631	.689	.070*	.006*	.043*
Age	.426	.384	.160	.942	.155
Female sex	.062*	.516	.940	.689	.128
BMI	.842	.948	.081*	.497	<.001*
Coronary artery disease	.001*	.256	.001*	.207	.005*
Diabetes	.075*	NS	.936	.097*	.372
Chronic renal dysfunction	NS	1.000	.903	NS	NS
COPD	.171	1.000	NS	.352	.566
Cerebrovascular accident	.677	.319	.760	.282	.284
Myocardial infarction	NS	1.000	.903	NS	NS
NYHA grade ≥III	NS	NS	.477	.613	.925
Malperfusion syndromes					
Myocardial	.627	NS	.522	.316	.656
Cerebral	.149	.099*	.832	.103	.315
Gastrointestinal	.052*	NS	.266	.034*	.094*
Lower extremity	.016*	NS	.042*	.006*	.013*
Creatinine >200 μmol/L	.029*	NS	.063*	.033*	.488
ALT or AST >100 IU/L	NS	NS	.634	.010*	.678
Bentall procedure	.407	.694	.463	.879	.339
CABG	.002*	.316	.001*	.067*	.002*
CPB time	.027*	.045*	<.001*	.002*	<.001*
Cross-clamp time	.032*	.038*	.028*	.111	.018*

AKI, Acute kidney injury; *ABO*, aortic balloon occlusion; *BMI*, body mass index; *NS*, not significant; *COPD*, chronic obstructive pulmonary disease; *NYHA*, New York Heart Association; *ALT*, alanine aminotransferase; *AST*, aspartate aminotransferase; *CABG*, coronary artery bypass grafting; *CPB*, cardiopulmonary bypass. *The factors with a *P* value of ≤.1 were included in multivariable regression analysis.

0.218; 95% CI, 0.084-0.561; $P = .002$), and grade II-III AKI (OR, 0.432; 95% CI, 0.204-0.915; $P = .028$) (Table 6).

DISCUSSION

TAR with FET has been widely used in China since Sun and colleagues introduced the technique in 2006.[13] The elephant-stented graft is used to expand the true lumen, improve thrombosis of the residual false lumen, and simplify the second-phase operation. In the ABO technique, we take full advantage of this stented graft by placing an aortic balloon in it to block the backflow from femoral cannulation. Generally, there is a little back bleeding when the balloon is properly positioned at the metal part of the elephant trunk and fully inflated, and any back bleeding that does occur can be removed with an aspirator. Another problem is that backflow may leak from the large false lumen. This can also be solved by adjusting the flow rate from CPB and sucking the blood away. We place the balloon in the stent graft, and the inner face is smooth enough so the balloon does not get punctured. With this technique, the CPB mode shifts from MHCA/ACP to moderate hypothermia (nasopharyngeal temperature 28°C) and transient circulatory arrest. With the significantly shortened circulatory arrest time, the most favorable temperature is under study. Because the 3 to 5 minutes of circulatory arrest is shorter than the duration of tolerance of warm ischemia of visceral organs, we think that mild hypothermia is feasible for aortic arch surgery with the ABO technique.

Although the circulatory arrest time was greatly reduced, the incidences of 30-day death and stroke and the composite adverse events were not lower in the ABO group compared with the conventional circulatory management strategy. A recent study of 1708 cases of aortic arch surgery found an elevated risk for permanent neurologic dysfunction and mortality when unilateral ACP time was >38 minutes and temperature was below approximately 24°C.[14] Thus, the average circulatory arrest time of 18.4 ± 3.1 minutes in the MHCA/ACP group is safe enough and is not associated

TABLE 6. Multivariable logistic analysis for risk factors associated with composite adverse events, stroke, ventilation time >24 h, hepatic dysfunction, and AKI grade II-III

Factor	OR (95% CI)	*P* value
Composite adverse events		
Coronary artery disease	5.992 (2.255-15.918)	<.001
Lower extremity malperfusion	7.184 (1.725-29.918)	.007
Stroke		
Cross-clamp time	1.015 (1.001-1.029)	.038
Ventilation time >24 h		
ABO	0.455 (0.234-0.887)	.021
Coronary artery disease	4.079 (1.518-10.957)	.005
CPB time	1.027 (1.013-1.042)	<.001
Cross-clamp time	0.976 (0.958-0.994)	.011
Hepatic dysfunction		
ABO	0.218 (0.084-0.561)	.002
Lower extremity malperfusion	5.462 (1.242-24.018)	.025
Gastrointestinal malperfusion	16.524 (1.368-199.546)	.027
ALT or AST >100 IU/L	6.902 (1.089-43.754)	.040
CPB time	1.013 (1.005-1.020)	.001
AKI grade II-III		
ABO	0.432 (0.204-0.915)	.028
BMI	1.177 (1.069-1.295)	.001
Coronary artery disease	2.676 (1.033-6.928)	.043
Lower extremity malperfusion	5.971 (1.354-26.326)	.018
CPB time	1.010 (1.003-1.017)	.006

OR, Odds ratio; *CI*, confidence interval; *ABO*, aortic balloon occlusion; *CPB*, cardiopulmonary bypass; *ALT*, alanine aminotransferase; *AST*, aspartate aminotransferase; *AKI*, acute kidney injury; *BMI*, body mass index.

with an increased risk of mortality and stroke. Furthermore, mortality and stroke are associated with a variety of factors, including age, New York Heart Association score, coma, malperfusion syndrome, coronary artery bypass grafting, and other factors identified by previous studies.[14-16] The ABO technique only changes the mode of extracorporeal circulation, and it is difficult for it to reverse the outcome of high-risk patients.

In our study, the average ventilator support time was shortened by more than 10 hours in the ABO group, and on multivariable analysis, patients in the ABO group were less likely to require ventilator support for >24 hours. In our institution, the protocol for weaning off ventilation is normally initiated as soon as consciousness is regained. We interpret this outcome as demonstrating faster recovery of brain function from the impact of hypothermia and anesthesia. Two previous studies comparing unilateral and bilateral ACP[17,18] and 2 other studies comparing arch surgery under 2 different levels of hypothermia,[19,20] reported reduced postoperative mechanical ventilation requirements for patients undergoing bilateral ACP and HCA at warmer temperatures. There are 2 possible reasons for our finding: that the neurologic injury related to hypothermia was reduced and that the duration of the brain's dependence on selective cerebral perfusion was shortened. When the femoral canula was reopened, the brain was perfused through the bifurcated arterial line, with blood flow to the brain and visceral organs distributed naturally according to vascular resistance, which was considered a more physiological perfusion model.

In the present study, the most obvious effect of the ABO technique was to reduce liver damage and predispose to low-grade AKI, although the temperature was raised significantly. This is because the new technique provides almost continuous blood flow to the liver and kidney compared with the conventional method. However, the ABO technique did not reduce the need for dialysis, just as the incidences of stroke and death did not decrease. Compared with conventional surgery, the ABO technique provides additional perfusion for the kidneys, but not sufficient to correct already impaired kidney function and prevent deterioration. There was no significant difference in the distribution of postoperative AKI grades between the 2 groups, possibly related to the small sample size.

The CPB and cross-clamp times were both longer in the ABO group compared with the MHCA/ACP group. A plausible explanation for this is that the ABO technique allows the surgeon to complete distal arch anastomosis without racing against the clock to shorten the time of circulatory arrest. In addition, it may be associated with the learning curve effect of this new technique.

This study has several inevitable limitations. First, the study is a retrospective review, and the results may be affected by its nonrandomized design. Second, surgeries for the 2 groups were performed by 2 different operating groups in our institution. Third, this study represents only a single-center experience, not a multicenter experience, and there are disparities across different surgeons and centers. Fourth, the number of patients in the study was relatively small; larger studies are needed.

CONCLUSIONS

The ABO technique allows the performance of TAR with FET under moderate hypothermia and transient circulatory arrest. Our present findings show that the ABO technique is not associated with the incidence of major adverse outcomes in the treatment of ATAAD but has certain protective effects on liver and kidney. Future large-sample, randomized, multicenter studies are warranted to thoroughly evaluate the efficacy of this new technique.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

We thank Ying Dong (National Center for Cardiovascular Diseases, Fuwai Hospital, China) for statistical assistance.

References

1. Shrestha M, Haverich A, Martens A. Total aortic arch replacement with the frozen elephant trunk procedure in acute DeBakey type I aortic dissections. *Eur J Cardiothorac Surg*. 2017;51(Suppl 1):i29-34.
2. Ma WG, Zhang W, Wang LF, Zheng J, Ziganshin BA, Charilaou P, et al. Type A aortic dissection with arch entry tear: surgical experience in 104 patients over a 12-year period. *J Thorac Cardiovasc Surg*. 2016;151:1581-92.
3. Ma WG, Zhang W, Zhu JM, Ziganshin BA, Zhi AH, Zheng J, et al. Long-term outcomes of frozen elephant trunk for type A aortic dissection in patients with Marfan syndrome. *J Thorac Cardiovasc Surg*. 2017;154:1175-89.e2.
4. Sun L, Qi R, Zhu J, Liu Y, Zheng J. Total arch replacement combined with stented elephant trunk implantation: a new ‘‘standard’’ therapy for type A dissection involving repair of the aortic arch? *Circulation*. 2011;123:971-8.
5. Czerny M, Schmidli J, Adler S, van den Berg JC, Bertoglio L, Carrel T, et al. Current options and recommendations for the treatment of thoracic aortic pathologies involving the aortic arch: an expert consensus document of the European Association for Cardio-Thoracic surgery (EACTS) and the European Society for Vascular Surgery (ESVS). *Eur J Cardiothorac Surg*. 2019;55:133-62.
6. Keeling WB, Tian DH, Leshnower BG, Numata S, Hughes GC, Matalanis G, et al. Safety of moderate hypothermia with antegrade cerebral perfusion in total aortic arch replacement. *Ann Thorac Surg*. 2018;105:54-61.
7. Tsai JY, Pan W, Lemaire SA, Pisklak P, Lee VV, Bracey AW, et al. Moderate hypothermia during aortic arch surgery is associated with reduced risk of early mortality. *J Thorac Cardiovasc Surg*. 2013;146:662-7.
8. El-Sayed Ahmad A, Papadopoulos N, Risteski P, Moritz A, Zierer A. The standardized concept of moderate-to-mild ($\geq$28°C) systemic hypothermia during selective antegrade cerebral perfusion for all-comers in aortic arch surgery: single-center experience in 587 consecutive patients over a 15-year period. *Ann Thorac Surg*. 2017;104:49-55.
9. Sun X, Guo H, Liu Y, Li Y. The aortic balloon occlusion technique in total arch replacement with frozen elephant trunk. *Eur J Cardiothorac Surg*. 2019;55:1219-21.
10. Ma WG, Zhu JM, Zheng J, Liu YM, Ziganshin BA, Elefteriades JA, et al. Sun’s procedure for complex aortic arch repair: total arch replacement using a tetrafurcate graft with stented elephant trunk implantation. *Ann Cardiothorac Surg*. 2013;2:642-8.
11. Yan TD, Tian DH, LeMaire SA, Hughes GC, Chen EP, Misfeld M, et al. Standardizing clinical end points in aortic arch surgery: a consensus statement from the International Aortic Arch Surgery Study Group. *Circulation*. 2014;129:1610-6.
12. Levey AS, Bosch JP, Lewis JB, Greene T, Rodgers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. *Ann Intern Med*. 1999;130:461-70.
13. Liu ZG, Sun LZ, Chang Q, Zhu JM, Dong C, Yu CT, et al. Should the ‘‘elephant trunk’’ be skeletonized? Total arch replacement combined with stented elephant trunk implantation for Stanford type A aortic dissection. *J Thorac Cardiovasc Surg*. 2006;131:107-13.
14. Wang X, Yang F, Zhu J, Liu Y, Sun L, Hou X. Aortic arch surgery with hypothermic circulatory arrest and unilateral antegrade cerebral perfusion: perioperative outcomes. *J Thorac Cardiovasc Surg*. February 14, 2019 [Epub ahead of print].
15. Conzelmann LO, Weigang E, Mehlhorn U, Abugameh A, Hoffmann I, Blettner M, et al. Mortality in patients with acute aortic dissection type A: analysis of pre- and intraoperative risk factors from the German Registry for Acute Aortic Dissection Type A (GERAADA). *Eur J Cardiothorac Surg*. 2016;49:e44-52.
16. Conzelmann LO, Hoffmann I, Blettner M, Kallenbach K, Karck M, Dapunt O, et al. Analysis of risk factors for neurological dysfunction in patients with acute aortic dissection type A: data from the German Registry for Acute Aortic Dissection Type A (GERAADA). *Eur J Cardiothorac Surg*. 2012;42:557-65.
17. Li B, Hu X, Wang Z. The neurologic protection of unilateral versus bilateral antegrade cerebral perfusion in aortic arch surgery with deep hypothermic circulatory arrest: a study of 77 cases. *Int J Surg*. 2017;40:8-13.
18. Tong G, Zhang B, Zhou X, Tao Y, Yan T, Wang X, et al. Bilateral versus unilateral antegrade cerebral perfusion in total arch replacement for type A aortic dissection. *J Thorac Cardiovasc Surg*. 2017;154:767-75.
19. Leshnower BG, Thourani VH, Halkos ME, Sarin EL, Keeling WB, Lamias MJ, et al. Moderate versus deep hypothermia with unilateral selective antegrade cerebral perfusion for acute type A dissection. *Ann Thorac Surg*. 2015;100:1563-8; discussion 1568-9.
20. Leshnower BG, Myung RJ, Thourani VH, Halkos ME, Kilgo PD, Puskas JD, et al. Hemiarch replacement at 28°C: an analysis of mild and moderate hypothermia in 500 patients. *Ann Thorac Surg*. 2012;93:1910-5; discussion 1915-6.

Key Words: aortic dissection, total arch replacement, frozen elephant trunk, aortic balloon occlusion