Comparison of open surgical versus hybrid endovascular repair for descending thoracic aortic aneurysms with distal arch involvement

Hyun-Chel Joo¹, Young-Nam Youn¹, Young-Guk Ko², Donghoon Choi², Jong Yun Won³, Do Yun Lee³, Kyung-Jong Yoo¹

¹Division of Cardiovascular Surgery, Department of Thoracic and Cardiovascular Surgery, ²Division of Cardiology, ³Division of Radiology, Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul, Republic of Korea

Contributions: (I) Conception and design: HC Joo, YN Youn, KJ Yoo; (II) Administrative support: YN Youn; (III) Provision of study materials or patients: HC Joo, YN Youn, YG Ko, DH Choi, JY Won, DY Lee; (IV) Collection and assembly of data: HC Joo, YN Youn, YG Ko, DH Choi, JY Won, DY Lee; (V) Data analysis and interpretation: HC Joo, YN Youn, JY Won, DY Lee, KY Yoo; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Young-Nam Youn, MD, PhD. Division of Cardiovascular Surgery, Severance Cardiovascular Hospital, Yonsei University College of Medicine, Yonsei University Health System, (120-752) 250 Seongsanno, Seodaemun-gu, Seoul, Republic of Korea. Email: ynyoun@yuhs.ac.

Background: Our aim was to compare the efficacies of conventional open thoracotomy and hybrid endovascular technique in patients with descending thoracic aortic aneurysms involving the distal arch.

Methods: Between January 2005 and December 2015, 125 consecutive patients with descending aneurysms involving distal arch underwent open repair via thoracotomy (n=79) or zone 1/2 hybrid endovascular repair (n=46). Surgeries entailing total arch replacement by elephant trunk technique (with sternotomy) and Zone 0 hybrid arch repairs were excluded. Early and late outcomes were compared using propensity scores and inverse-probability-of-treatment weighting (IPTW).

Results: In-hospital mortality rates for open repair (10.1%) and hybrid repair (6.5%) did not differ significantly (P=0.49). Major adverse outcomes included stroke (11.4% vs. 8.7%), paraplegia (2.5% vs. 0.0%) and lung complications (19.0% vs. 6.5%). Once adjusted by IPTW, hospital mortality risk for conventional open repair (OR =4.396; P=0.086) tended to be higher, and there was significant risk of lung complications (OR =4.372; P=0.025). However, both techniques were similar in terms of 30-day mortality (OR =2.745; P=0.257), stroke (OR =2.134; P=0.217), paraplegia (OR =3.639; P=0.407), and midterm survival (OR =1.05; P=0.90). Freedom from reintervention at 10 years was significantly better for open repair (85.2% \pm 7.1%) compared with the hybrid approach (46.3% \pm 11.0%; OR =0.13; P<0.01).

Conclusions: Hybrid arch repair conferred a significantly lower incidence of pulmonary complications, without benefitting perioperative mortality and stroke. However, open repair proved more reliable, showing greater durability. Long-term investigations are needed to confirm the viability and safety of hybrid repair as an alternative treatment in this setting.

Keywords: Hybrid surgery; descending aorta; distal arch aneurysm

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Introduction

Isolated pathology of the descending aorta at present is managed safely and effectively through open or thoracic endovascular aortic repair (TEVAR). Open repair is an established and durable therapeutic option (1,2), whereas TEVAR is a newer alternative surgical repair option that offers acceptable results for high-risk patients (3-5). However, disease of the descending aorta that extends proximally to the arch is inherently more complex. There are hazards associated with accessing the arch during open repair, and endovascular repair requires a hybrid technique.

Open surgical repair of lesions involving the arch calls for total circulatory arrest (TCA), cerebral perfusion, and manipulation of arch atheroma, all contributing to the high risk of this procedure. A hybrid technique that combines supra-aortic vascular debranching with stent grafting of the aortic arch has been introduced as an attractive therapeutic alternative. Still, the short- and long-term outcomes of hybrid repairs remain unclear due to technical difficulties and complications imposed by supra-aortic vascular angulation and influences (6-10).

Several studies to date have examined both hybrid and conventional open repairs (via sternotomy) in managing arch aneurysms, although none have similarly addressed thoracotomy and hybrid repairs of descending thoracic aorta (DTA) that include the distal arch (11-13). A preferred approach has therefore yet to be determined. We thus sought to compare outcomes of conventional open (thoracotomy) and hybrid arch repairs in patients with descending aortic aneurysms, focusing on those that involve the distal arch.

Methods

Patient population

Between January 2005 and December 2016, 125 patients underwent descending aortic surgical repairs inclusive of the distal arch at the Yonsei Cardiovascular Hospital of Yonsei University Health System in Seoul, Republic of Korea. The patients were grouped by procedure, 79 (63.2%) undergoing conventional open repair via thoracotomy (open group) and 46 (36.8%) subjected to hybrid aortic repair (hybrid group). Surgeries entailing total arch replacement by elephant trunk technique (with sternotomy) and Zone 0 hybrid arch repairs were grounds for exclusion.

The hybrid group included those patients whose hybrid arch repairs incorporated supra-aortic branch

revascularization and involved at least one common carotid artery bypass and simultaneous or staged endovascular thoracic stent grafting. As a prerequisite for successful stentgraft placement, a proximal landing zone of healthy and non-dissected aorta (or polyester graft) of at least 20 mm along the curvature of aortic arch and a diameter <40 mm at the level of proximal landing zone were stipulated. The decision for hybrid arch repair was based on discussions between cardiac and vascular surgeons, interventional cardiologists, and vascular radiologists.

Operative techniques

Conventional open repair

Each patient underwent hemi-arch and descending aortic replacement via left thoracotomy. Surgical access was via left 4th or 5th intercostal space. Left femoral artery and vein were routinely cannulated to establish cardiopulmonary bypass. Left ventricular venting was achieved via left low pulmonary vein or left ventricular apex, and TCA was induced at a core body temperature of 20 °C, without cerebral perfusion or cardioplegia. We performed routine electroencephalogram (EEG) monitoring, which served as the basis for initiating TCA. Bladder temperature was used as a core index for systemic organ protection.

Hybrid arch repair

The operations were performed under general endotracheal anesthesia with continuous monitoring by transesophageal echocardiography (TEE), rSO_2 , and arterial pressure. Five patients (12.8%) underwent one-stage procedures. Two-stage procedures, performing TEVAR after full recovery from cervical debranching, were conducted in another 32 patients (87.2%). Cervical debranching was achieved through cervicotomy, enabling supra-tracheal right-to-left common carotid artery bypass using an 8-mm Gore-Tex or Dacron graft. A carotid clamp was placed under rSO_2 monitoring, but in no instance was a carotid shunt required. All TEVAR procedures were confined to a hybrid room, furnished with both endovascular and surgical equipment. The common femoral artery was regularly used for access in placing of stent grafts.

Classification

Aortic arch zones were designated according to Ishimaru¹⁴ as follows: Zone 0, ascending aorta proximal to innominate artery; Zone 1, aortic arch between innominate and left

common carotid artery; Zone 2, aortic arch between left common carotid artery and left subclavian artery (LSCA); Zone 3, proximal DTA distal to LSCA; and Zone 4, mid-DTA (14).

Endpoints and definitions

The primary study endpoints were early (in-hospital) and late mortality. Operative morbidities, including neurologic complications and reinterventions, constituted secondary endpoints. A reintervention was defined as any surgical or endovascular procedure for any complication related to the aorta in the aftermath of the primary procedure. Spinal cord ischemia (SCI) corresponded with any newly acquired lower-extremity deficit unrelated to an intracerebral event. SCIs were considered permanent if symptoms were not completely resolved at the time of discharge. Stroke was marked by any new global or focal neurologic deficit lasting more than 24 h, with an acute lesion observed on brain imaging. Technical success was equated with successful introduction and deployment of a device in the absence of mortality, surgical conversion, type I or III endoleaks, or graft limb obstruction.

Data collection and follow-up monitoring

Preoperative and perioperative data were collected prospectively from cardiac and vascular research databases at our institution. More detailed data on clinical outcomes and long-term survival were obtained by reviewing hospital charts or through telephone interviews. The Institutional Review Board of Yonsei University College of Medicine approved the study (Yonsei Institutional Review Board No. 4-2014-0810), waiving the customarily required individual patient consent. The protocol called for follow-up clinical examinations and computerized tomography (CT) scans done before discharge, at 6 months, and then annually thereafter.

Statistical analyses

All data were expressed as mean \pm standard deviation (SD) or frequency and percentage. Continuous variables were compared via Student's *t*-test, using x^2 or Fisher's exact test to compare categorical variables. To reduce the impact of selection bias and potential confounding factors, we adjusted the patient characteristics by using weighted logistic regression analysis and inverse-probability-of-

treatment weighting (IPTW). Goodness-of-fit was assessed through Hosmer and Lemeshow chi-square test. Longterm survival and freedom of reintervention curves were estimated by Kaplan-Meier method, using log-rank test to compare differences. In all statistical testing, significance was defined as a two-tailed P value <0.05. Statistical analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC, USA) and R, version 3.3.0 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient characteristics

Patient demographics and clinical risk factors of the two groups are summarized in Table 1. Prior to adjustment, patient age in the hybrid (vs. open) group appeared significantly greater (64.8±13.9 vs. 58.2±14.8 years; P=0.015), and the percentage of patients with chronic obstructive pulmonary disease tended to be higher (hybrid: 17.4%, 8/46; open: 7.6%, 6/79; P=0.091), as did histories of previous aortic surgery (hybrid: 23.9%, 11/46; open: 12.7%, 10/79; P=0.105). In contrast, maximum aneurysm size was significantly greater in the open (vs. hybrid) group (63.3±10.9 vs. 59.4±10.2 mm; P=0.042). In examining the extent of arch and DTA involvement, proximal DTA lesions accounted for a sightly higher proportion in the hybrid group by comparison (hybrid: 45.7%, 21/46; open: 32.9%, 26/79; P=0.156). After adjustment, however, baseline characteristics and distributions within the two groups were found to be well balanced.

Operative data

Conventional open repair

Each patient underwent hemi-arch and DTA replacement via left thoracotomy. TCA was performed in 62 patients (78.5%) and aortic cross clamping (between subclavian and carotid arteries) was performed in 17 patients (21.5%). Mean TCA time was 16.2 ± 6.1 min, and mean nadir of body temperature was 24.6 ± 4.2 °C. LSCA sacrifice was done in six patients. Details of open repair are summarized in *Table 2*.

Hybrid arch repair

Twenty-two patients (47.8%) underwent cervical debranching procedures, including right-to-left carotid bypass. LSCA revascularization was performed in 38

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Characteristics -	Unadjusted data			Data adjusted by IPTW		
Characteristics –	Group 1 (n=79)	Group 3 (n=46)	P value	Group 1 (n=79)	Group 3 (n=46)	P value
Age (year)	58.2±14.8	64.8±13.9	0.015	62.5±14.5	62.7±15.1	0.937
Gender	19 (24.1%)	7 (15.2%)	0.241	23.6	15.6	0.309
Smoking	39 (49.4%)	25 (54.3%)	0.591	51.1	48.9	0.817
HTN	56 (70.9%)	36 (78.3%)	0.367	73.7	77.1	0.681
CAOD	22 (27.9%)	18 (39.1%)	0.192	30.4	31.5	0.896
DM	10 (12.7%)	6 (13.0%)	0.950	13.9	12.2	0.793
CRF	22 (27.9%)	16 (34.8%)	0.416	30.8	29.9	0.917
ESRD	2 (2.5%)	2 (4.3%)	0.625	2.2	4.1	0.535
Old CVA	8 (10.1%)	6 (13.0%)	0.618	11.1	10.9	0.978
COPD	6 (7.6%)	8 (17.4%)	0.091	8.6	11.2	0.640
Preoperative eGFR	73.1±28.6	68.0±25.3	0.320	70.8±28.5	71.2±26.6	0.929
Maximum aortic size	63.3±10.9	59.4±10.2	0.042	61.9±13.5	58.0±12.6	0.124
Emergency	11 (13.9%)	4 (8.7%)	0.386	13.8	10.0	0.555
Dissection	25 (31.6%)	20 (43.5%)	0.184	36.9	40.5	0.701
Marfan syndrome	8 (10.1%)	3 (6.5%)	0.745	8.4	9.1	0.908
Pre-aortic surgery	10 (12.7%)	11 (23.9%)	0.105	29.4	25.7	0.817
Arch involvement			0.703			0.990
Zone 1	35 (44.3%)	22 (47.8%)		45.6	45.7	
Zone 2	44 (55.7%)	24 (52.2%)		54.4	54.3	
DTA involvement						
Proximal	26 (32.9%)	21 (45.7%)	0.156	35.4	39.1	0.680
Mid	38 (48.1%)	19 (41.3%)	0.462	46.8	43.5	0.710
Distal	15 (19.0%)	6 (13.0%)	0.391	17.7	17.4	0.960

IPTW, inverse-probability-of-treatment weighting; HTN, hypertension; CAOD, coronary artery obstructive disease; DM, diabetes mellitus; CRF, chronic renal failure; ESRD, end-stage renal disease; CVA, cerebrovascular accident; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; DTA, descending thoracic aorta.

patients (82.6%). Staged procedures were conducted in 36 patients (78.3%), with 22 patients (47.8%) undergoing Zone 1 TEVAR. Preoperative drainage of cerebrospinal fluid (CSF) was undertaken in 15 patients (32.6%). The types of stents used for TEVAR were as follows: Seal (S&G Biotech Inc., Seoul, Republic of Korea); Valiant (with Captivia delivery system; Medtronic, Santa Rosa, CA, USA); and Cook TX2 device (Cook Medical Inc., Bloomington, IN, USA). Details of the hybrid procedures are summarized in *Table 3*.

Early outcomes

Unadjusted early perioperative outcomes are summarized in *Table 4*. There were no early open conversions for failed hybrid procedures. In-hospital mortality did not differ significantly by group (open: 10.1%, 8/79; hybrid: 6.5%, 3/46; P=0.49), and strokes occurred with similar frequency (open: 11.4%, 9/79; hybrid: 8.7%, 4/46; P=0.63). In two patients, conventional open repair resulted in paraplegia, compared with none in the hybrid group, but the difference was not significant (P=0.27). Postoperative morbidity

Table 2 Details	of conventional open repair	procedures
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Variables	Open repair (n=79)
Left thoracotomy	79 (100%)
TCA	62 (78.5%)
Mean TCA time (min)	16.2±6.1
Mean temperature nadir (°C)	24.6±4.2
LSCA sacrifice	6 (7.6%)
LSCA bypass	5 (6.3%)
ICA reimplantation	10 (12.7%)
Preoperative CSF drainage	21 (26.6%)

TCA, total circulatory arrest; LSCA, left subclavian artery; ICA, intercostal artery; CSF, cerebrospinal fluid.

Table 3 Details of hybrid procedures

Variables	Hybrid repair (n=46)
Carotid-carotid-LSCA bypass	18 (39.1%)
Carotid-carotid bypass	4 (8.7%)
Carotid-LSCA bypass	21 (45.7%)
Carotid-LSCA interposition	1 (2.2%)
LSCA sacrifice	6 (13.0%)
One stage	10 (21.7%)
Staged procedure	36 (78.3%)
Proximal landing zone	
Zone 1	22 (47.8%)
Zone 2	24 (52.2%)
Preoperative CSF drainage	15 (32.6%)

LSCA, left subclavian artery; CSF, cerebrospinal fluid.

rates recorded for lung complications (open, 19.0%; hybrid, 6.5%; P=0.04) and vocal cord palsy (open, 22.8%; hybrid, 2.2%; P<0.01) proved to be significantly higher in those undergoing conventional open repair. Adjusted ORs of adverse outcomes in open and hybrid groups are summarized in *Table 5*. After IPTW adjustment, there were no significant differences in 30-day mortality and perioperative stroke (P=0.257 and P=0.217, respectively). However, compared with the hybrid group, the risk of hospital mortality tended to be higher for the open group (OR =4.396; 95% CI: 0.811–23.816; P=0.086), and risk of lung complications was significantly higher (OR =4.372, 95% CI: 1.200–15.935; P=0.025) (*Figure 1*).

Long-term survival and reintervention

Mean follow-up duration was 51.9 ± 34.9 months (range, 1–116 months). The two groups did not differ significantly in this regard (open: 50.3 ± 33.9 months; hybrid: 54.6 ± 36.6 months; P=0.50), nor did overall survival rates at 10 years (open: $59.4\%\pm8.8\%$; hybrid: $48.8\%\pm10.8\%$; P=0.299, unadjusted; P=0.929, adjusted) (*Figure 2*). In the hybrid group, 16 (34.8%) patients required reintervention or surgery, including endovascular reintervention in 12 patients and open conversion for aneurysm enlargement (n=2) or retrograde type A dissection (n=2). Subsequently, the freedom from reintervention rates at 10 years differed significantly (open: $85.2\%\pm7.1\%$; hybrid: $41.3\%\pm11.3\%$; P<0.01, unadjusted; P<0.01, adjusted) (*Figure 3*).

Discussion

In patients with disease of the descending aorta and distal arch involvement, optimal treatment is unclear, given the current lack of data. There are no studies to date comparing thoracotomy and hybrid techniques in such scenarios. Based on the present investigation, it is apparent that hybrid repairs carry equivalent early and late mortality risk, surpassing conventional open repair by virtue of fewer pulmonary complications and shorter ICU or hospital stays. However, the hybrid approach seems less durable than open repair.

Potential negative side-effects of thoracotomy for aortic arch lesions

Although clinical outcomes of open repair have been well documented in isolated DTA segments, such documentation is lacking for distal arch involvement. Okita et al. showed that atherosclerotic arch lesions accompanying descending thoracic aneurysms introduce considerable risk, affecting early mortality and stroke rates (15). Thoracotomy increases the chance of embolic events. When the arch is opened during deep hypothermic arrest, without aortic clamping, the embolic burden of an atherosclerotic arch may disperse retrograde into carotid vessels, leading to embolic strokes (16). Even if the arch is clamped, it inevitably requires manipulation, again posing the threat of embolic stroke. The current study findings likewise linked early mortality in the thoracotomy group to embolic events such as stroke or coronary embolism, associated with manipulation of arch lesions.

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Variables	Open repair (n=79)	Hybrid repair (n=46)	P value
Technical success	79	46	NS
In-hospital mortality	8 (10.1%)	3 (6.5%)	0.49
30-day mortality	6 (7.6%)	2 (4.3%)	0.47
Reoperation for bleeding	6 (7.6%)	2 (4.3%)	0.47
Stroke	9 (11.4%)	4 (8.7%)	0.63
Paraplegia	2 (2.5%)	0 (0.0%)	0.27
Newly required dialysis	8 (10.1%)	2 (4.3%)	0.25
Lung complications	15 (19.0%)	3 (6.5%)	0.04
Vocal cord palsy	18 (22.8%)	1 (2.2%)	<0.01
ICU stay (day)	6.8±8.4	3.5±5.2	0.02
Hospital stay (day)	20.6±16.6	13.1±8.8	<0.01

 Table 4 Early outcomes (unadjusted)

ARF, acute renal failure; ICU, intensive care unit.

Table 5 Odds ratio (OR) of major adverse event of convention:	al open vs.	. hybrid re	pair (adjusted l	oy IPTW)
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Outcomes		95	Dyelve		
Outcomes	Un	Lower bound	Upper bound	r value	
Hospital mortality	4.396	0.811	23.816	0.086	
Mortality at 30 days	2.745	0.480	15.713	0.257	
Reoperation for bleeding	2.104	0.376	11.778	0.397	
Newly required CRRT	2.494	0.617	10.089	0.199	
Lung complication	4.372	1.200	15.935	0.025	
Stroke	2.134	0.640	7.114	0.217	
Paraplegia	3.639	0.172	77.109	0.407	

IPTW, inverse probability of treatment weighting; CRRT, continuous renal replacement therapy.

Pulmonary complications associated with thoracotomy are readily acknowledged as consequences of aortic arch repair and reportedly are as high as 30% (17). In the present study, the incidence of pulmonary complications after conventional open repair was significantly higher than that following hybrid surgery (open: 19%, 15/79; hybrid: 6.5%, 3/46; P=0.04). The demands of prolonged mechanical ventilation and tracheostomy have greater impact in the context of open (*vs.* hybrid) repair. It is thought that lung manipulation during thoracotomy is a source of parenchymal bleeding and edema; and vocal cord palsy may promote further pulmonary compromise owing to aspiration or impaired bronchial toilet. These findings demonstrate that when arch lesions are involved, an open (i.e., thoracotomy) approach is fraught with potential risks, particularly embolic events or lung complications, which may contribute to perioperative mortality.

Potential negative side-effects of bybrid arch repair

There are inherent difficulties in endovascular procedures as well, because aortic arch characteristics/properties, including its angulation, high-velocity blood flow, and substantial pulsatile movement, are apt to be problematic. According to previous studies, arch lesions are more often subject to type



Figure 1 Forrest plot of adjusted odds ratios for early and long-term outcomes of conventional open and hybrid repair procedures.



Figure 2 Kaplan-Meier curves comparing of overall survival in conventional open (red line) and hybrid (black line) repair groups (unadjusted and adjusted).



Figure 3 Kaplan-Meier curves comparing freedom from reintervention in conventional open (red line) and hybrid (black line) repair groups (unadjusted and adjusted).

I endoleaks than are isolated TEVAR procedures (18-20). Our results proved similar to outcomes of reintervention or open conversion, with 75% (12/16) of type I endoleaks or new entry tears occurring at proximal lesion endografts. Stent migration may also occur more frequently in arch lesions. As mentioned above, the combination of angulation and high-velocity flow are key factors in stent migration after hybrid arch repair. On one occasion, stent migration and type I endoleak presented 2 years after a hybrid arch repair. The patient was treated by reintervention.

Finally, retrograde type I dissection (RTAD) may rarely develop after TEVAR. RTAD has been reported at rates of 1–2% after TEVAR (21-23). In hybrid arch repairs, the incidence of RTAD appears to be higher than after single TEVAR procedures (19). Recently Gandet *et al.* reported that in 32 patients undergoing hybrid arch repairs, six experienced RTAD (18.7%) (24). Again, factors such as severe angulation, high-velocity flow, and pulsatile movement may contribute to the development of RTAD. In the current study, the incidence of RTAD after hybrid repairs was 4.3% (2/46). Of note, RTAD may occur during initial procedures or in the course of follow-up monitoring. One year postoperatively, RTAD was discovered by CT scan in one of our patients, who then required emergency surgery.

Comparing early outcomes of open and hybrid repairs

The superiority of any approach in treating diseases of the descending aorta that involve the arch is still debatable. Although many sources credit hybrid repairs with less invasiveness, there is little research that truly validates any claimed advantages over conventional open repair. As cited in earlier reports, outcomes of hybrid arch (*vs.* open) repair may be more favorable in terms of operative morbidities and early recovery (11-13). Herein, we have also shown that pulmonary complications are reduced and that ICU or hospital stays are shortened.

It is important to note that stroke and early mortality percentages after hybrid repairs are still high. In a metaanalysis undertaken by Moulakakis *et al.*, stroke (7.6%) and mortality (11.6%) rates for hybrid arch repair showed no significant improvement relative to open approach (25). Despite certain advantages (fewer pulmonary or renal complications and reduced ICU/hospital stays), we similarly discovered no distinct mortality (open: 10.1%; hybrid: 6.5%; P=0.49) or stroke (open: 11.4%; hybrid: 8.7%; P=0.63) benefits. Three of our patients suffered early mortality after hybrid repairs, two dying of massive cerebral infarction and the other of sudden death due to hemothorax; and all occurred after TEVAR procedures. Five strokes were also recorded in the aftermath of TEVAR, but none after debranching. Hence, it appears that the endovascular aspect of a hybrid approach to diseased arch lesions is implicated in the ominous outcomes (i.e., stroke or death) thereafter.

Limitations of hybrid strategy reintervention

Reintervention is unquestionably required more often after endovascular aortic repair than after open repair. Hybrid strategies also have limitations in terms of long-term endograft durability. After hybrid arch repair, reintervention rates range from 0-30% (6-14). In our study, 16 patients (34.8%) in the hybrid group required reintervention or open surgery for various reasons, such as type I or II endoleak, stent migration, and RTAD. Hybrid arch repairs were also associated with significantly higher percentages of reintervention during a 10-year follow-up period, compared with open repair [34.8% (16/46) vs. 7.6% (6/79); P<0.01]; and such complications may occur at any time. In our study, five reinterventions performed >4 years after hybrid aortic repairs were necessitated by type I endoleaks and stent migration. Moreover, one patient died suddenly from a recurring type I endoleak (while awaiting open conversion), having previously survived reintervention after Zone 1 TEVAR. Although many late complications of hybrid arch repairs may be resolved through endovascular technique, patients with no hope of endovascular salvage will need open conversion to avoid sudden death. The findings herein suggest that long-term survival of patients undergoing hybrid arch repairs may decline over time.

Study limitations

This study has several clear limitations. Its retrospective design imparts selection bias. Not all patients with aortic aneurysms were anatomically suited for hybrid repair, adding further to selection bias. There was also heterogeneity of patient characteristics, aortic pathologies, and degrees of involvement. Nevertheless, the latter were minimized by focusing on descending aortas with arch involvement. The relatively small number of patients recruited was another limitation.

Conclusions

Outcomes of both open and hybrid surgical techniques were

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satisfactory. Hybrid arch repair conferred a significantly lower incidence of pulmonary complications, but without apparent benefits for midterm survival and perioperative stroke. However, open repair proved more reliable, showing greater durability than hybrid repair. Long-term follow-up is needed to confirm the viability and safety of hybrid repair as an alternative treatment in this setting.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The Institutional Review Board of Yonsei University College of Medicine approved the study (Yonsei Institutional Review Board No. 4-2014-0810), waiving the customarily required individual patient consent.

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