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Complications after treatment of type B aortic dissection with TEVAR stent-graft deployment in zone 2

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Abstract

Objective To analyze the outcome of 147 cases of type B aortic dissection with thoracic endovascular aortic repair (TEVAR).

Methods We systematically reviewed 147 patients of type B aortic dissection with stent graft deployment in zone 2 or zone 3 by TEVAR from January 2012 to December 2022. These patients were observed by computed tomography angiography after the first and third months and annually thereafter during follow-up. Statistical analysis was performed by SPSS.16.

Results The stent graft of 107 patients was deployed in zone 3, and the stent graft of 40 patients was deployed in zone 2. Severe dissection and surgery-related complications after TEVAR occurred in 19 patients, with complications arising more frequently in zone 2 than in zone 3 (12/40 vs. 7/107, $P<0.005$). Endoleak was detected in 10 (6.8%, 10/147) cases, which included 6 cases of endoleak in zone 2, exceeding the 4 cases of endoleak in zone 3 (6/40 vs. 4/107, $P<0.05$). Twelve (8.16%, 12/147) cases underwent re-intervention, and the 8 patients who underwent re-intervention in zone 2 exceeded the 4 patients who underwent re-intervention in zone 3 (8/40 vs. 4/107, $P<0.05$). One case of subclavian steal in zone 2 (0.68%, 1/147). Two (1.36%, 2/147) cases died after TEVAR. The 1-year, 3-year, and 5-year overall survival rates were 99.3%, 98.6%, and 98.6%, respectively. The re-intervention rates were 5.4%, 7.5%, and 8.2%, respectively. The re-intervention rates in zone 2 were 15%, 20%, and 20%, respectively. The re-intervention rates in zone 3 were 1.9%, 2.8%, and 3.7%, respectively.

Conclusion TEVAR is the major treatment to use if the stent graft can be deployed in zone 3. However, with the higher rate of complications and re-intervention after TEVAR, for patients whose stent graft can only be deployed in zone 2, it is not recommended that TEVAR be chosen as the preferred treatment.

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Article highlights

Type of Research: Single-center retrospective cohort study.

Key findings: 147 patients of type B aortic dissection with stent graft deployed in zone 2 or zone 3 by TEVAR. Severe dissection and surgery-related complications after Thoracic EndoVascular Aortic Repaie (TEVAR) occurred in 19 patients, with complications arising more frequently in zone 2 than in zone 3 (12/40 vs. 7/107, $P<0.005$). Endoleak was detected in 10 (6.8%, 10/147) cases, which included 6 cases of endoleak in zone 2, exceeding the 4 cases of endoleak in zone 3 (6/40 vs. 4/107, $P<0.05$). Twelve (8.16%, 12/147) cases underwent re-intervention, and the 8 patients who underwent re-intervention in zone 2 exceeded the 4 patients in zone 3 (8/40 vs. 4/107, $P<0.05$). The 1-year, 3-year, and 5-year overall survival rates were 99.3%, 98.6%, and 98.6%, respectively. The re-intervention rates were 5.4%, 7.5%, and 8.2%, respectively. The re-intervention rates in zone 2 were 15%, 20%, and 20%, respectively. The re-intervention rates in Zone 3 were 1.9%, 2.8%, and 3.7%, respectively.

Take Home Message: This study suggests that TEVAR is the major treatment to use TEVAR if the stent graft can be deployed in zone 3. However, with the higher rate of complications and re-intervention after TEVAR, for patients whose stent graft can only be deployed in zone 2, it is not recommended that TEVAR be chosen as the preferred treatment.

Keywords TEVAR, Type B aortic dissection, Stent graft, Endoleak

Introduction

Thoracic endovascular aortic repair (TEVAR) aims to address the primary endothelial breach and remodel the aortic outcome by deploying a membrane-covered stent graft in the lesion to prevent further enlargement of the lesion and eventual rupture of the aorta [1]. TEVAR has gained attention as a minimally invasive treatment option for type B dissection due to its ability to reduce surgical complications [2]. The study's results indicated the ratio of thrombotic occlusion, which happened in the false lumen of the descending aorta, greater than 90% in case the primary breach is closed by stent grafting during the initial period of the disease. In post-operative reports of TEVAR, common complications include vascular complications at the puncture site, aortic and neurologic complications, and endoleaks.

Controversies exist regarding TEVAR for aortic dissection, particularly in the acute phase, including the appropriate length of the stent graft, the ideal location for proximal implantation, and the optimal type of stent graft.

We classified the proximal placement of stent graft in TEVAR according to the Ishimaru criteria (zone 2: aortic arch, distal to the left common carotid artery, including the origin of the left subclavian artery, zone 3: aortic arch, distal to the origin of the left subclavian artery), to further compare the complications of stenting after implantation of a stent graft in patients with type B aortic dissection in landing zone 2 and 3 (Fig. 1).

Patients and methods

Patients

This is a retrospective study. Between January 2012 and December 2022, 147 patients (Table 1) diagnosed with type B aortic dissection via computed tomography angiography and treated with TEVAR at the First Affiliated Hospital of Xiamen University were included in this study. Approval for the study was obtained from the Clinical Research Ethics Committee of the First Affiliated Hospital of Xiamen University. The Clinical Trial Number is No.SL-2023KY030-01. Informed consent was obtained from all subjects or their legal guardian(s).

Inclusion criteria were:1. complicated acute type B aortic dissection, including branch-vessel malperfusion, impending rupture, aortic diameter ≥ 40 mm, rapid aortic expansion, and persistent pain or hypertension despite maximal medical therapy, who underwent emergency TEVAR [3–8]. 2. scheduled TEVAR after two weeks of conservatively acute type B aortic dissection. Patients who were at high operative risk, inoperable, or refused surgery were excluded. Patients with high surgical risk are those who have a limited life expectancy due to advanced age combined with other systemic diseases that are more intolerable to surgery or combined with poor organ perfusion, active aortitis, pregnancy, aortic constriction, etc. We usually choose open surgery or conservative treatment according to the patient's condition.

Methods

All patients had documented computed tomography angiography, with the distance from the tear to the left subclavian artery, and the diameter of the landing zone being measured by multidetector computed tomography and 3-D reconstruction (Fig. 2). Implanted stents are stent-graft (Medtronic, USA) or Zenith stent-graft (Cook, USA). Aortic stent graft distal oversize rate (Oversize) is the ratio between the diameter of the chosen stent graft and the diameter of the aortic vessel in the anchorage area in TEVAR. In our case, the proximal Oversize was selected with a stent caliber of 0–5%, and the distal size was selected based on the patient's preoperative CTA

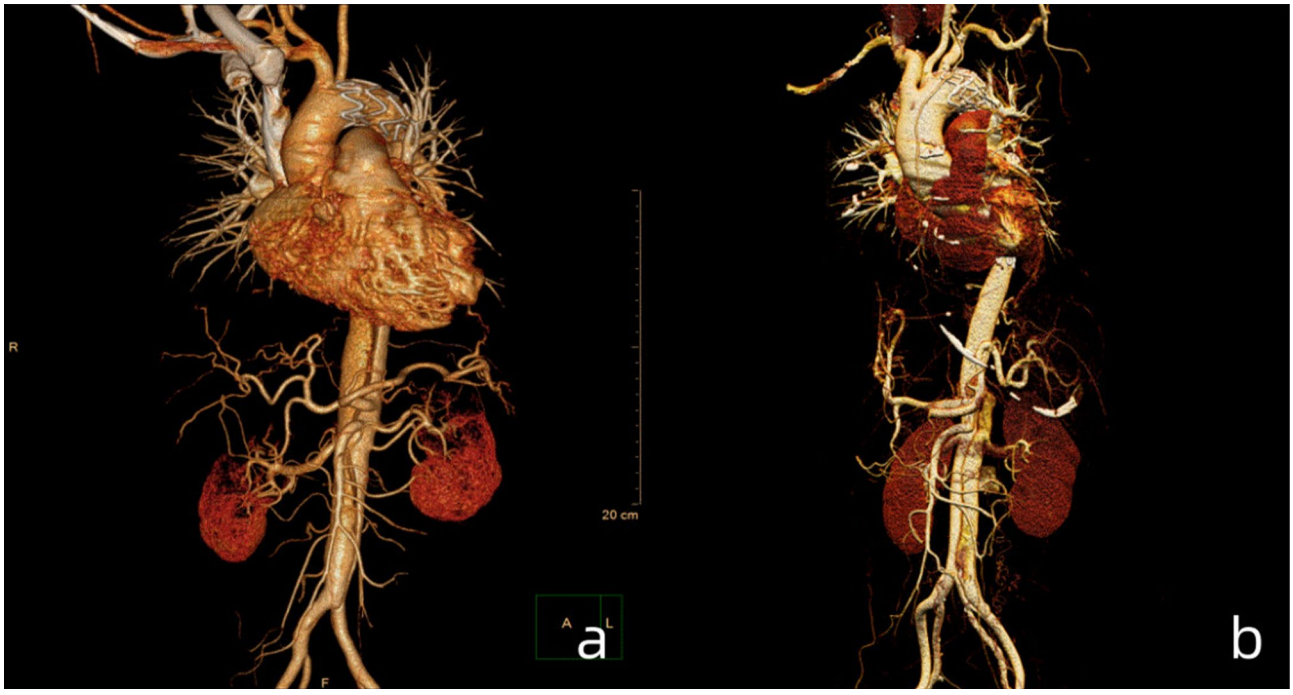

Fig. 1 **A**: Stent graft deployed in Landing Zone 2; **B**: Stent graft deployed in Landing Zone 3

Table 1 Patients characteristics

Characteristics	Zone 2 (*n* = 40)	Zone 3 (*n* = 107)	P
Age (y)	54.5	62	0.04
Male Gender	23(57.5%)	87(81.3%)	0.07
Smokers	22(55%)	78(72.9%)	0.08
Hypertension	25(62.5%)	76(71.0%)	0.33
Diabetes mellitus	7(17.5%)	24(22.4%)	0.65
Chronic renal failure	3(7.5%)	15(14.0%)	0.4
Coronary heart disease	14(35%)	55(51.4%)	0.1
Peripheral vascular disease	9(22.5%)	23(21.5%)	1
Chronic obstructive pulmonary disease	7(17.5%)	29(27.1%)	0.28
Emergency surgery	7(17.5%)	23(21.5%)	0.65
Elective operation	33(82.5%)	84(78.5%)	0.65
Mean follow-up time	61.8	63.13	<0.01

results. A tapered stent was selected if there was significant compression of the true lumen combined with false lumen thrombosis [8–10]. Angiography was repeated after the implant of the stent graft to identify if there was endoleak or malperfusion of the left subclavian artery, left vertebral artery, and essential branches of the abdominal aorta. In technical terms in surgery, success is measured by how well the device is introduced and placed, and there must be no surgical conversions, deaths, or type I or III endoleaks.

Follow-up

These patients were followed by computed tomography angiography after the first and third months and annually thereafter during follow-up. The presence of an endoleak, endoleak type, false lumen thrombosis, organ malperfusion, and aortic measurements were recorded. The false lumen is considered to be patent if contrast is present in it during the arterial or venous phase of computed tomography angiography. Pre-operative and post-operative measurements were taken at different levels to determine the minor axis diameter of the real lumen, false lumen, and total aorta.

Statistical analysis

SPSS.16 (SPSS, Inc., Chicago, IL; 2016) was used for statistical analysis. Descriptive statistics are presented suitably: categorical data are expressed as frequencies (percentage); continued data are expressed as average ± standard deviation or median (range). Unpaired Student's t-test was utilized to compare means from values with Gaussian distribution. Mann-Whitney test was used to compare values without a Gaussian distribution. Categorical data were compared using the chi-squared test. The probability of re-intervention and other endpoint events occurring in zones 2 and 3 was described using the Kaplan-Meier method and analyzed comparatively using the Log-Rank test.

Results

Between January 2012 and December 2022, a total of 147 patients diagnosed with type B aortic dissection underwent TEVAR (Table 2), whose median age was 61 years (range 34–88 years), and 110 of the 147 (74.83%) patients

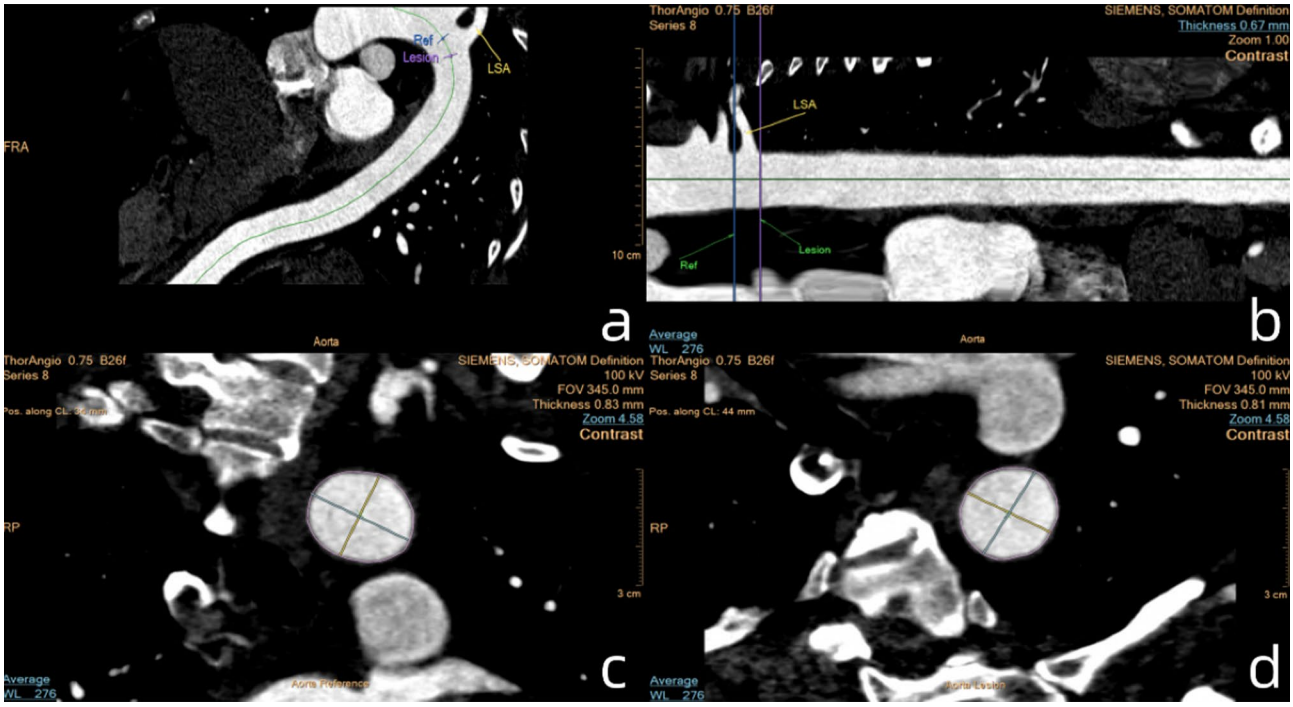

Fig. 2 Measurement of aortic diameters in landing zone 2 and 3. A green line (a central line) must be drawn to obtain strict perpendicular measurements to the aortic axis. We use the maximum diameter of the landing zone from intima to intima if the cross-sectional shape of the lumen at the landing zones is elliptical or even crescentic rather than circular, (maximum blue line + minimum yellow line diameter/2) is aortic diameters of the landing zone (LSA: left subclavian artery; Ref: cross-section of the landing zone 2; Lesion: cross-section of the landing zone 3)

Table 2 Complications and aortic events in 19 Cases

Patient	Gender	Age	landing zone	Complication	Time to complication	Reintervention	Outcome
No.1	F	56	Zone 2	Ia Endoleak	Soon	EVR	S
No.2	F	50	Zone 2	Ia Endoleak	Soon	EVR	S
No.3	M	63	Zone 2	Ia Endoleak	Soon	EVR	S
No.4	M	76	Zone 2	Ib Endoleak	Soon	EVR	S
No.5	F	59	Zone 2	II Endoleak	3 month	-	S
No.6	M	47	Zone 2	RTAD	2 week	OS	S
No.7	F	67	Zone 2	RTAD	1 month	OS	S
No.8	M	50	Zone 2	FLD	27 month	OS	S
No.9	F	73	Zone 2	FLD	12 month	OS	S
No.10	M	60	Zone 2	II Endoleak	1 month	-	S
No.11	M	63	Zone 2	-	1 month	-	D
No.12	M	58	Zone 3	Ia Endoleak	Soon	EVR	S
No.13	F	57	Zone 3	II Endoleak	1 month	-	S
No.14	F	67	Zone 3	IV Endoleak	1 month	-	S
No.15	M	63	Zone 3	Ib Endoleak	3 month	EVR	S
No.16	F	66	Zone 3	FLD	45 month	OS	S
No.17	M	74	Zone 3	FLD	12 month	OS	S
No.18	M	71	Zone 3	-	13 month	-	D
No.19	M	70	Zone 2	SS	33 month	-	S

*M:Male; F:Female; D:Death; S:Survive; EVR:Endovascular Repair; OS: Open Surgery; RTAD: Retrograde type A Dissection; FLD:False Lumen Dilatation;SS:Subclavian Steal

were men. The mean follow-up time was 62.77 months (range 6-130 months, with a mean follow-up time of 61.80 months for zone 2 and 63.13 months for zone 3, $P<0.01$).

Among 147 cases of type B aortic dissection treated with TEVAR (Figs. 1), 30 cases underwent emergency operation because of branch-vessel malperfusion, impending rupture, rapid aortic expansion, persistent pain, or hypertension despite maximum medical therapy, 117 cases were treated with scheduled TEVAR after two weeks of best medical therapy(BMT) for acute type B aortic dissection. The stent graft of 107 cases were treated with stent graft deployment landing zone 3, and 40 cases were deployed in zone 2 (including 8 (20%, 8/40) cases of left subclavian artery revascularization by bypass).

During the follow-up period, aortic events and surgery-related complications appeared in 19 (12.93%, 19/147) cases after TEVAR (Table 2). The incidence of complications in landing zone 2 is higher than that in landing zone 3 (12/40 vs. 7/107, $P<0.05$) (Table 3). In particular, the endoleak rate for the zone 2 group was 15%, retrograde type A aortic dissection occurred in 5%, and aortic re-interventions were necessary in 20%.

Endoleaks

Endoleak was detected in 10 (6.8%,10/147) cases, of which 2 (6.67%, 2/30) cases were in the emergency surgery group, and 8 (6.84%, 8/117) cases were in the elective surgery group. 6 (15%, 6/40) cases developed endoleak in zone 2, and 4 (3.74%,4/107) cases were detected in zone 3, $P<0.05$. Type Ia endoleak was detected in 4 (2.72%, 4/147) cases, including 3 cases of stent graft deployment in zone 2 and 1 case in zone 3. Type Ib endoleak was detected in 2 (1.36%, 2/147) cases, including 1 case of stent graft deployment in zone 2 and 1 case in zone 3. Type II endoleak was detected in 3 (2.04%, 3/147) cases, including 2 cases of stent graft deployment in zone 2 and 1 case in zone 3. Type IV endoleak was detected in 1 (0.68%, 1/147) case of sent deployment in zone 3.

Table 3 Complications of 147 Cases

Complications	Zone 2 ($n=40$),n(%)	Zone 3 ($n=107$),n(%)	P
Endoleak	6(15.00)	4(3.74)	< 0.05
Ia Endoleak	3 (7.50)	1 (0.93)	-
IbEndoleak	1 (2.50)	1 (0.93)	-
II Endoleak	2 (5.00)	1 (0.93)	-
III Endoleak	0 (0)	0 (0)	-
IV Endoleak	0 (0)	1 (0.93)	-
Subclavian steal	1(2.50)	0(0)	-
Paraplegia	0 (0)	0 (0)	-
Stroke	0 (0)	0 (0)	-
Retrograde type A dissection	2 (5.00)	0 (0)	-
Reintervention	8 (20.00)	4 (3.74)	< 0.01
Endovascular repair	4 (10.00)	2 (1.87)	< 0.05
Open surgery	4 (10.00)	2 (1.87)	< 0.05
Death in hospital	1 (2.50)	1 (0.93)	> 0.05

Re-interventions

Re-intervention occurred in 12 (8.16%, 12/147) patients, including 8 (20%, 8/40) cases in zone 2 and 4 (3.74%, 4/107) cases in zone 3, $P<0.01$. The cumulative incidence of aortic re-intervention at 1 year after TEVAR with landing in zone 2 was 15%, compared with 1.7% for aortic re-intervention landing in zone 3. The incidence at 5 years was 20% and 3.7%, $P<0.01$. Four cases of type Ia endoleak and 2 cases of type Ib endoleak were successfully repaired by using the endovascular technique. Two cases of retrograde type A dissection and four cases of false lumen dilatation at the distal stent graft end were successfully repaired by open surgery. There were 10 (83.33%, 10/12) cases of stent-related re-interventions, including 6 (60%, 6/10) cases of distal stent-related re-interventions. The type I endoleak was the primary determining factor of proximal stent-related re-interventions (40%,4/10).

Hospital morbidity

There were two (1.36%,2/147) in-hospital patient deaths, including one case in zone 2, who died of spontaneous aortic dissection, and the other one in zone 3, who died of acute myocardial infarction. No obvious evidence was found to confirm that death was associated with surgical procedures. No paraplegia or stroke occurred in all patients.

Discussion

Introduced in the early 1990s, TEVAR has progressed and improved over the years to become a widely recognized technique for the treatment of patients with thoracic aortic pathologies [11–13]. Nevertheless, as the number of TEVAR procedures and the length of postoperative monitoring increase, the occurrence of re-intervention for issues after thoracic aortic TEVAR is becoming more frequent [14–18]. Our study found that stent graft deployment in Zone 2 had a higher complication rate than in Zone 3. Therefore, conventional TEVAR faces significant challenges when stent graft are placed in zone 2. When TEVAR is used to treat supra-aortic arch lesions, how to effectively protect the cerebral circulation and quickly and safely reconstruct the supra-arch branches is the difficulty of treatment at this stage.

Endoleak (mainly proximal type I endoleak) remains an Achilles heel of endovascular aortic dissection repair because of the bottleneck of achieving a proximal seal between the endograft and the distal aortic arch, the incidence of which is 5–38%. After computed CT angiography confirms the presence of endoleak, the standard course of treatment has been to aggressively repair type

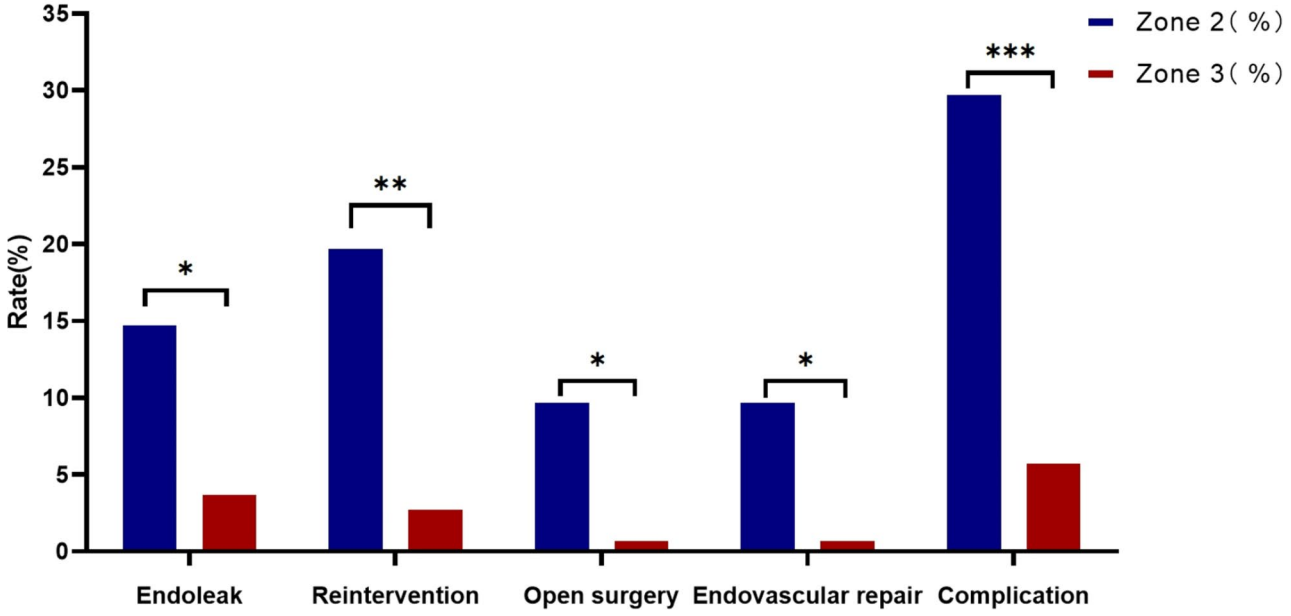

Fig. 3 Complication rates of type B aortic dissection after TEVAR with stent deployment in zone 2 VS zone 3 (*$P < 0.05$, **$P < 0.01$)

I and type III endoleak and monitor type II and type IV endoles [17]. The incidence of endoleak is 6.8% (10/147). Computed tomography angiography revealed that 4 cases of type Ia endoleak were detected, 3 of which occurred in zone 2 and 1 in zone 3. Type Ib endoleak was detected in 2 cases. For those patients, a straightforward balloon angioplasty of the endograft at the attachment site should be used to expand the stent graft more entirely so that they adapt to the aorta wall and create a sufficient seal. If this fails, the proximal or distal connection sites may be secured with bare stent graft or endograft extensions. The incidence of endovascular repair is significantly higher in Zone 2 than in Zone 3, with rates of 10% (4 out of 40) and 1.87% (2 out of 107), respectively ($P < 0.05$) (Fig. 3). 4 cases of type II and type IV endoleak disappeared during the follow-up period.

When complications occur in patients with acute type B aortic dissection, such as intractable pain, refractory hypertension, impending rupture, poor organ perfusion syndrome, progressive mediastinal hematoma, and pleural effusion, they should be treated with TEVAR in an emergency. The study's results by Wojciechowski J et al. suggest that LSA revascularization is not mandatory before endograft transplantation, especially in emergencies [19]. However, more experts have emphasized the importance of protecting the antegrade flow of not just the IA and LCCA but also the LSA in treating arch disease with TEVAR. Chong Li et al. concluded that the use of in situ laser fenestration(ISLF) during TEVAR is safe and effective. The advantage is that it allows the preservation of the antegrade flow of arch branches in a single-stage operation as well as the swift treatment of complex aortic arch disease under emergent circumstances. Due to the tortuous path of the branch vessels and excessive intervention during the procedure, ISLF may damage the integrity of the original stent graft, increasing the risk of endoleaks and cerebrovascular accidents. A Meta-analysis by Xiyang Chen et al. concluded that performing LSA revascularization reduced the risk of stroke, paraplegia, and left upper limb ischemia [20]. Bradshaw et al. suggested that coverage of the left subclavian artery without revascularization increased the risk of stroke [21]. Some researchers have chosen to perform CSB or SCT for LSA revascularization while covering the left subclavian artery to restore blood flow in the left subclavian artery, thereby reducing the incidence of cerebrovascular accidents. However, this approach carries risks of increased surgical time, difficulty, blood loss, increased incidence of anastomotic stenosis, nerve injury, wound hematoma, lymphatic leakage, and the risk of endoleaks [21–25]. Eight patients in our research who haven't received left subclavian artery coverage with revascularization by bypass and 32 patients who haven't received it did not suffer a stroke. This may be related to the small number of cases we had, the presence of underlying disease in the patients, and the quality of the arteries (absence of calcification and plaque in the target vessel), among others.

The causes for re-intervention are endoleak (especially type I and type III), stent graft fracture, false lumen dilatation at the distal stent graft end, retrograde type A dissection, distal stent graft–induced new tear, stent migration and infection of stent-graft [8, 18, 26–31]. Re-intervention is generally divided into two categories: stent-related re-intervention and nonstent-related

re-intervention. Re-intervention related to the stent graft included those associated with the stent graft or treatment area. According to the location of the lesion relative to the stent graft, it can be divided into three subgroups (proximal, adjacent, and distal). Nonstent-related re-intervention involves procedures performed both above the arch and below the thoracoabdominal aorta. Stent-related re-intervention occurred more frequently than nonstent-related re-intervention, with rates of 83.3% (10 out of 12) and 16.7% (2 out of 12), respectively. Amongst stent-related re-interventions, distal causes were relatively common (60%, 6/10) compared to proximal (40%, 4/10). The distal complication arose due to the occurrence of type Ib endoleak and the expansion of the false lumen in the distal region or the emergence of new tears generated by the distal stent graft. Type I endoleak was the primary factor influencing the need for re-intervention in proximal stent graft cases.

TEVAR-related mortality included deaths as a result of aneurysm rupture, surgical conversion, or complications of TEVAR unsolved by other operations [3]. Two (1.36%, 2/147) in-hospital patient deaths after TEVAR, and there is no direct evidence that the operation resulted in death. One case died of spontaneous aortic dissection, and the cause of the rupture is unknown. Some studies suggested that the correct size of the stent graft and severe blood pressure control after TEVAR can prevent aortic rupture. The other one died of acute myocardial infarction. The types of potential risk factors were analyzed: history of chest tightness or chest pain, coronary artery calcification, unusual electrocardiogram, and myocardial enzyme. Preoperative patients should routinely undergo coronary angiography.

According to the European registry on endovascular aortic repair complications, 54% of the documented instances of retrograde aortic dissection happened following the endovascular treatment of an acute type B aortic dissection [28]. Regarding retrograde dissection, which has a mortality rate of 42%, many potential risk factors increase the risk of retrograde entrapment after implantation for these complex aortic arch disorders, especially in acute or subacute settings. Types of potential risk factors for retrograde type A dissection were analyzed: damage to the aortic wall during TEVAR, stent graft proximal landing zone (landing zones 0, 1, and 2, respectively), stent graft excessive oversizing (more than 20% of the diameter of the landing zone), compliant balloon angioplasty, indexed aortic diameter, loss of the sinusoidal junction and presence of an aortic arch malformation and so on. Some scholars have used branch stent-graft to cover the left subclavian artery and anchor it in Zone 2 and chosen to fenestrate at the location of the left subclavian artery to reconstruct blood flow. In-situ fenestration reconstruction of the LSA is an effective and feasible approach in patients with TEVAR with restricted proximal anchorage area, requiring adequate experience and proven technique and specific equipment by the operator, with a high rate of technical success, but still with the risk of endoleak and cerebrovascular accidents [32–35]. It is worth mentioning that the Castor Stent Graft was invented by Dr. Lu Qingsheng in China and is currently widely used for complex Type B dissections involving Zone 2. Early follow-up of this technique is satisfactory, with a low incidence of complications such as endoleak, retrograde entrapment, and stroke. Still, because the stent graft used to require a period of customization, averaging 6–8 weeks, they are suitable for elective surgery in patients with reasonable financial means [36]. In addition, the prospective, multicentre study protocol of the WeFlow-Arch modular inner branch stent-graft system, hosted by Dr. Guo Wei's team in China, proposes that the design concept of the modular inner branch stent-graft system ensures that cerebral blood flow is not compromised during surgical operations, which can effectively avoid the need for deep hypothermia arrest and open-heart surgery, and reduce the risk of stroke [37]. There is no long-term follow-up data, and further validation is needed.

In summary, the endovascular repair of complex Type B dissections involving Zone 2 is currently a hot topic worldwide. However, various branch stent-graft techniques and surgical approaches are limited and have not gained unanimous recognition. The long-term follow-up complication rate of branch stent graft anchoring in Zone 2 is relatively high, particularly in younger patients with a longer expected survival period. Therefore, there is an urgent need for professional researchers to invent a single or multi-branch aortic branch stent graft that has the advantages of simple deployment, accurate branch alignment, low incidence of endoleaks, no customization required, and low prices to meet the needs of these patients. Interventional treatment with the Castor Single Stent Graft can be considered for better-off patients with stable conditions. For young patients with complicated conditions, stenting and reconstruction of the left subclavian artery or even the left common carotid artery through SUN's procedure is recommended.

This was a retrospective single-center series that took place over a long observation period and it has a few limitations. Firstly, it did not identify or analyze comorbidities and independent risk factors because the disease categories were diverse and the patient's medical records were incomplete. Secondly, the study retrospectively analyzed a small sample of patients who used heterogeneous follow-up computed tomography angiography intervals.

Conclusion

TEVAR has been increasingly used to treat acute and chronic aortic dissections, particularly in patients with comorbidities, to avoid these patients at high risk of open aortic surgical repair. Treatment of type B aortic dissection with TEVAR and stent graft deployment in zone 3 was associated with fewer complications than in zone 2. TEVAR is the primary treatment for using TEVAR if the stent graft can be deployed in zone 3. However, with the higher rate of complications and re-intervention after TEVAR, for those patients whose stent graft can only be deployed in zone 2(especially those young patients who are in tolerance of operation), it is not recommended to choose TEVAR as the preferred treatment.

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Author contributions
XB.Z. prepared the research program and original manuscript. X.C. conducted the data collection and analysis and worked with XB.Z. on the main manuscript. Z.W, R.L, and M.S provided the analytical equipment and recorded the data. DQ.C. and ZH.C validated the data. GY.C. and L.L describe the analysis results. QX.X and QX.X performed the charting. J.H and JW.Z revised the manuscript. ZG.S. and ZH.Z. supervised and obtained funding for this study. All authors approved the final version and consented to publication.

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Data availability
All data generated or analyzed during this study are included in the manuscript and supplemental materials, and questions regarding the datasets used or analyzed in the study can be directed to the corresponding author.

Declarations

Ethics approval and consent to participate
This study was approved by the Medical Ethics Committee of the First Affiliated Hospital of Xiamen University. The Clinical Trial Number is No.SL-2023KY030-01. Informed consent was obtained from all subjects or their legal guardian(s).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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