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CLINICAL ARTICLE

Intracranial Aneurysms Managed by Parent Artery Reconstruction Using Tubridge Flow Diverter study: 1-year outcomes

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OBJECTIVE Previous randomized controlled trials have reported a significantly higher occlusion rate of large and giant aneurysms when utilizing the Tubridge flow diverter (FD). In the present trial, the safety and efficacy of the Tubridge FD in treating unruptured internal carotid artery (ICA) or vertebral artery (VA) aneurysms were assessed in a real-world setting.

METHODS The Intracranial Aneurysms Managed by Parent Artery Reconstruction Using Tubridge Flow Diverter (IMPACT) study is a prospective, multicenter, single-arm clinical trial assessing the efficacy of the Tubridge FD in the management of unruptured aneurysms located in the ICA or VA. The primary endpoint was the complete occlusion (Raymond-Roy class 1) rate at the 1-year follow-up. The secondary endpoints included the technical success rate, the successful occlusion rate of the aneurysm, which is the degree of aneurysm embolization scored as Raymond-Roy class 1 or 2, major (> 50%) in-stent stenosis, and incidence of disabling stroke or neurological death associated with the target aneurysms.

RESULTS This study included 14 interventional neuroradiology centers, with 200 patients and 240 aneurysms. According to angiographic core laboratory assessment, 205 (85.4%) aneurysms were located in the ICA, 34 (14.2%) in the VA, and 1 (0.4%) in the middle cerebral artery. Additionally, 189 (78.8%) aneurysms were small (< 10 mm). At the 12-month follow-up, the total occlusion rate was 79.0% (166/210, 95% CI 72.91%–84.34%). Additionally, the occurrence of disabling stroke or neurological death related to the specified aneurysms was 1% (2/200).

CONCLUSIONS The 1-year results from the IMPACT trial affirm the safety record of use of the Tubridge FD in the treatment of intracranial aneurysms in real-world scenarios. These results reveal low morbidity and mortality rates of 3.5% and 1.5%, respectively. Furthermore, they provide evidence of the effectiveness of the Tubridge FD, as demonstrated by the complete occlusion achieved in 166 of 210 (79%) cases.

Clinical trial registration no.: ChiCTR2000032282 (Chinese Clinical Trial Registry)

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KEYWORDS Tubridge; flow diverter; intracranial aneurysms; small aneurysms; endovascular neurosurgery; vascular disorders

ABBREVIATIONS DSA = digital subtraction angiography; FAS = full analysis set; FD = flow diverter; ICA = internal carotid artery; IMPACT = Intracranial Aneurysms Managed by Parent Artery Reconstruction Using Tubridge Flow Diverter; mRS = modified Rankin Scale; PPS = per-protocol set; TFD = Tubridge flow diverter; VA = vertebral artery.

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A flow diverter (FD) is a modality for treating aneurysms that shifts the treatment's focus from deconstruction of the aneurysm to reconstruction of the parent vessel.[1] Nowadays, the FD is widely accepted as an optimal treatment strategy for large and giant intracranial aneurysms.[2] With the increasing application of FDs in the endovascular management of intracranial aneurysms, the indication of FDs has been expanded to small aneurysms, distal aneurysms, bifurcation aneurysms, and other types.[3]

The Tubridge FD (TFD) is a self-expanding nickel-titanium device with flared ends. A large TFD (diameter ≥ 3.5 mm) is braided with 62 nickel-titanium microfilaments and 2 platinum-iridium radiopaque microfilaments, whereas a smaller TFD (diameter < 3.5 mm) is composed of 46 nitinol and 2 platinum-iridium microfilaments (Fig. 1). The length of the TFD ranges from 10 to 45 mm, and the diameter ranges from 2.5 to 6.5 mm. In 2018, the TFD was developed by MicroPort NeuroTech and approved by the National Medical Products Administration for large and giant wide-neck internal carotid artery (ICA) and vertebral artery (VA) aneurysms. In the PARAT trial, the outcomes of the treatment of large and giant aneurysms with TFD were compared with those of conventional stent-assisted coiling, indicating the efficacy and safety of the TFD.[4] However, prospective data on TFD in real-world clinical scenarios are still insufficient. In addition, the properties of nickel-titanium FDs and their differences from cobalt-chromium FDs remain controversial. The Intracranial Aneurysms Managed by Parent Artery Reconstruction Using Tubridge Flow Diverter (IMPACT) trial is a prospective, multicenter, single-arm trial that aimed to evaluate the safety and efficiency of TFD for treating unruptured ICA or VA aneurysms (aneurysm neck width ≤ 20 mm, including saccular, fusiform, and dissecting aneurysms).[17]

Methods

Study Design and Participants

IMPACT is a postmarket clinical trial conducted to evaluate the outcomes of intracranial aneurysms treated with TFD at 14 interventional neuroradiology centers in China. This trial adhered to the ethical guidelines of the Declaration of Helsinki and received approval from the ethics boards of all participating institutions. Written informed consent was obtained from all participants.

Prospective subjects at each center were screened for trial eligibility based on the presence of an unruptured ICA or VA aneurysm (aneurysm neck width ≤ 20 mm), as confirmed by digital subtraction angiography (DSA), CTA, or MRA. Patients with target aneurysms previously treated with coiling or stent-assisted coiling within 90 days prior were excluded. Detailed inclusion and exclusion criteria are provided in the Supplemental Data.

Study Endpoints

The primary endpoint was the complete occlusion rate at the 12-month follow-up. The complete occlusion rate was defined as the percentage of subjects with Raymond-Roy class 1 aneurysm embolization (i.e., 100% aneurysm embolization).[18] Secondary endpoints included the following: 1) technical procedure success rate, defined as the deployment of a TFD that fully covered the aneurysm neck, achieved proper wall apposition, and preserved patency of the parent artery (TFD apposition was assessed using flat-plane rotational angiography); 2) successful aneurysm occlusion rate, defined as the percentage of subjects with Raymond-Roy class 1 or 2 aneurysm embolization (i.e., 95%–100% aneurysm embolization), assessed at the 12-month follow-up; 3) rate of major (> 50%) in-stent stenosis, defined as any lumen loss within the implanted TFD (calculated by measurement of the gap between the contrast-filled vessel lumen and the metal mesh of the stent), at the 12-month follow-up; 4) retreatment rate for target aneurysms during the follow-up period; 5) incidence of disabling stroke, characterized as a clear cerebral infarction or liquefaction focus accompanied by persistent neurological dysfunction (modified Rankin Scale [mRS] score ≥ 3), or neurological death associated with the target aneurysms, as well as all-cause mortality, at the 12-month follow-up; and 6) changes in mRS score (measured both before and 6 months after the procedure).

Procedural Modalities

All TFD implantations were performed under general anesthesia using a transfemoral approach. After sheath insertion, heparin was administered to maintain an active clotting time of 250–300 seconds throughout the procedure. Subsequently, a suitable guiding catheter was placed into the distal ICA or VA. The TFD was then implanted alone, as dual or multiple TFDs, or combined with bare coils. In addition, coils were required in three conditions: 1) aneurysms with irregular shape, 2) higher risk of delayed rupture after flow diversion (jet inflow, large size but with relatively narrow neck), and 3) giant or fusiform aneurysms in which coils could provide support for the FD. The dual antiplatelet therapy regimen recommended in the IMPACT trial was the administration of 300 mg of aspirin orally daily and 75 mg of clopidogrel orally daily for at least 3 days before the procedure. Postoperative antiplatelet therapy recommendations were as follows: ≤ 6 weeks: 300 mg of aspirin + 75 mg of clopidogrel; 6 weeks to 3 months: 100 mg of aspirin + 75 mg of clopidogrel; and ≥ 3 months: 100 mg of aspirin indefinitely. The ultimate antiplatelet regimen was determined by investigators.

All serious adverse events were independently evaluated by the Clinical Event Committee, consisting of one vascular neurosurgeon and two interventional neuroradiologists. The imaging results were independently evaluated by a core laboratory comprising three interventional neuroradiologists who determined the primary and secondary efficacy endpoints by assessing and correlating the angiograms based on the Raymond-Roy Occlusion Classification. The investigators' judgment regarding the patients' imaging results was solely used to guide the patients' clinical treatment and select subsequent treatment. This trial was registered on the Chinese Clinical Trial Registry (ChiCTR2000032282).

Data Collection

All data were collected prospectively using a main-

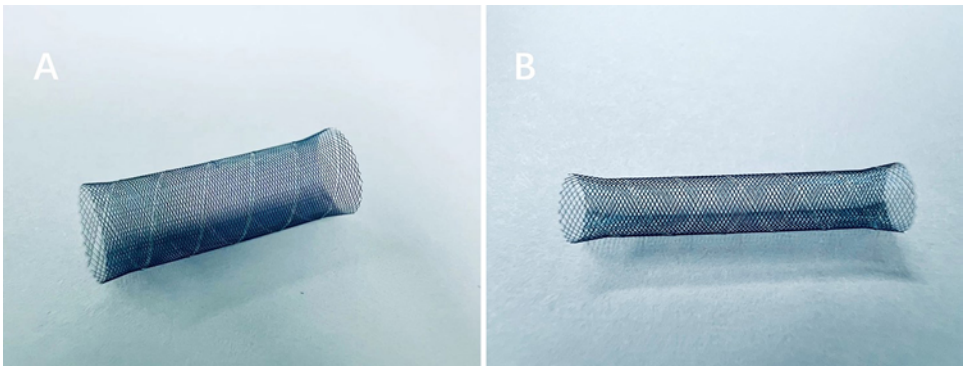

FIG. 1. A: Large TFD. **B:** Small TFD. © MicroPort NeuroTech Co. Ltd., published with permission. Figure is available in color online only.

tained electronic database with the following data: patient age and sex; aneurysm status (ruptured or unruptured), location, morphology, diameter, neck size, dome-to-neck ratio, and previous treatment; FD size; perioperative complications and antiplatelet medications; and use of additional devices during the procedure (e.g., coils and balloons).

Clinical evaluation, including determining the mRS score, was performed before treatment, at hospital discharge, and at 30 days, 6 months, and 12 months postprocedure. DSA examination was performed at the 12-month follow-up. If the participants refused the DSA examination, CTA or MRA examination was recommended. Additionally, data from retreatment procedures were also collected.

Statistical Analysis

The full analysis set (FAS) included all enrolled and treated participants. Participants who completed the entire treatment protocol with no protocol deviations and who had primary outcome data available were considered the per-protocol set (PPS). The safety set included participants who underwent FD implantation and had available postprocedural safety evaluation data. Analysis of the primary outcome (complete occlusion rate at 12-month follow-up) was based on both FAS and PPS. The 95% confidence interval for the complete occlusion rate at the 12-month follow-up was calculated using the exact probability test. Based on previous research with the Pipeline embolization device, the complete occlusion rate at 12 months in this trial was expected to be 80%, while the target value was set at 70%.[19,20] If the lower bound was > 70% (the target value), TFD was deemed effective for meeting clinical standards. In addition, a tipping-point sensitivity analysis was conducted to analyze the primary outcomes. The secondary efficacy outcomes (successful occlusion rate at 12 months) were based on actual data obtained from FAS. Continuous variables were presented as mean ± standard deviation, while categorical variables were presented as frequency and percentage. Logistic regression analyses were performed to ascertain autonomous forecasters of angiographic results. Aneurysm characteristics and occlusion rates were determined on a per-aneurysm basis, as some patients had more than one aneurysm treated with a single TFD. Statistical analysis was performed using SAS (version 9.4 and higher, SAS Institute).

Ethics Approval

Ethics approval for this research was obtained from the Shanghai Changhai Hospital Ethics Committee and from Beijing Tiantan Hospital, Capital Medical University.

Results

Patient and Aneurysm Characteristics

Between December 16, 2019, and October 26, 2022, 200 consecutive participants with 240 aneurysms were enrolled in the FAS based on the modified intention-to-treat principle. Among them, 22 were lost to the primary endpoint follow-up, 3 died, and 2 did not meet the inclusion criteria (one participant's aneurysm was located in the middle cerebral artery and another participant's aneurysm was ruptured). The remaining 173 participants were included in the PPS.

Table 1 summarizes participant demographics and aneurysm characteristics. The mean age of the participants was 57 ± 11.25 years, and 137 (68.5%) were women. Medical history most commonly included hypertension, hyperlipidemia, and diabetes mellitus. Ten (5%) patients had a history of aneurysmal subarachnoid hemorrhage. A total of 165 patients had a single aneurysm, while 35 patients had tandem aneurysms. The characteristics of the target aneurysm were assessed by an independent core angiographic laboratory. In total, 205 (85.4%) aneurysms were located in the ICA, 34 (14.2%) in the VA, and 1 (0.4%) in the middle cerebral artery. The mean diameter of the target aneurysm measured 7.35 ± 5.73 mm. Of the 240 aneurysms, 189 (78.8%) were categorized as small (< 10 mm), 45 (18.8%) were considered large (≥ 10 mm and < 25 mm), and 6 (2.5%) as giant (≥ 25 mm).

Procedure Results

As shown in Table 2, the technical procedure success rate was 99% (198/200 participants). A second salvage stent was implanted in 2 participants because of stent malapposition or failure to adequately cover the aneurysm neck. In total, 206 TFDs were deployed, with a single TFD in 82.08% (197/240) and ≤ 2 TFDs in 84.58% (203/240) of aneurysms. The mean number of devices used for each aneurysm was 0.86 ± 0.27. The surgeons opted for adjuvant coils in 19.58% (47/240) of the aneurysms.

TABLE 1. Baseline characteristics of the participants and aneurysms

	Value
Participant characteristics (n = 200)	
Age, yrs	57.0 ± 11.25
Female sex	137 (68.5)
Baseline mRS score	0.2 ± 0.45 (0–4)
Medical history	
Hypertension	100 (50.0)
Hyperlipidemia	14 (7.0)
Diabetes mellitus	14 (7.0)
Subarachnoid hemorrhage	10 (5.0)
Cerebral infarction	10 (5.0)
Coronary atherosclerotic cardiopathy	11 (5.5)
Arrhythmia	3 (1.5)
Allergy	10 (5.0)
Smoking status	
Current smoker	10 (5.0)
Past smoker	10 (5.0)
Alcohol use	11 (5.5)
Aneurysm characteristics (n = 240)	
Aneurysm size, mm	7.35 ± 5.73
<10	189 (78.8)
10 to <25	45 (18.8)
≥25	6 (2.5)
Neck width, mm	5.26 ± 3.02
Dome-to-neck ratio	1.42 ± 0.8
Aneurysm location	
ICA	205 (85.4)
C1	3 (1.3)
C2	2 (0.8)
C4	25 (10.4)
C5	41 (17.1)
C6	107 (44.6)
C7	27 (11.3)
VA	34 (14.2)
V2	1 (0.4)
V4	33 (13.8)
Middle cerebral artery	1 (0.4)
Aneurysm morphology*	
Saccular	211 (89.4)
Fusiform	25 (10.6)
Aneurysm type	
Single	165 (68.8)
Tandem	75 (31.3)

Values are presented as number (%), mean ± SD, or mean ± SD (range).
* The morphology of 4 aneurysms was absent.

TABLE 2. Treatment characteristics

	Value
Technical procedure success	198/200 (99)
No. of TFDs deployed	206
No. of TFDs per aneurysm	0.86 ± 0.27
1	197/240 (82.08)
≤2	203/240 (84.58)
Adjunctive coils placed	47/240 (19.58)

Values are presented as number (%) or mean ± SD.

Primary Endpoints

One-year anatomical outcomes were assessed in 175 of 200 (87.5%) patients. The vascular imaging technique was DSA in 159 of 175 (90.86%), MRA in 4 of 175 (2.29%), and CTA in 12 of 175 (6.86%) patients. The presence of artifacts in the images made the evaluation of parent artery patency in 8 cases unfeasible.

In the primary endpoint analysis, of the 173 patients with 210 aneurysms in the PPS cohort, the complete occlusion rate at the 12-month follow-up was 79.0% (166/210, 95% CI 72.91%–84.34%) (Fig. 2). Among the 25 patients who did not attain the primary endpoint, a sensitivity analysis of the said endpoint was conducted. The outcomes are presented in Table 3. The rationales behind the absence of primary endpoint data were categorized as follows: refusal to undergo radiological examination (n = 3), loss during imaging follow-up (n = 19), death (n = 3), or breach of the study protocol (n = 2). Table 4 provides a summary of the 12-month complete aneurysm occlusion rates concerning aneurysm categorization, dimensions, and treatment approach. Logistic regression analysis did not unveil any noteworthy variances in the complete occlusion rate concerning aneurysm categorization, dimensions, and treatment strategy, as outlined in Supplemental Table 1.

Secondary Outcomes

Table 4 presents the outcomes related to secondary measures. According to the FAS, the rate of successful aneurysm occlusion (defined as Raymond-Roy class 1 or 2) at the 12-month follow-up was 88.3% (188/213, 95% CI 83.16%–92.26%). Univariable and multivariable logistic regression analyses were conducted to identify the factors that predict aneurysm nonocclusion. The presence of a branch arising from the sac or neck was a predictor of aneurysm persistence in both analyses (Supplemental Table 2). Major (> 50%) in-stent stenosis was identified in 6 of 167 (3.6%) cases among the 175 of 200 (87.5%) participants who underwent angiography at the 12-month follow-up; it should be noted that the parent arteries of 8 participants could not be assessed. The incidence of disabling stroke or neurological death attributed to the target aneurysms was 1% (2/200). Throughout the follow-up period, the overall mortality rate was 1.5% (3/200). Furthermore, none of the target aneurysms required retreatment, while 4 of 200 (2%) participants underwent retreatment of the target vessels due to in-stent stenosis. The retreatment details are as follows: 2 patients underwent balloon dilation, 1 patient underwent Enterprise stent (Codman Neurovascular) implantation, and 1 patient underwent balloon dilation in addition to stent implantation. The mean

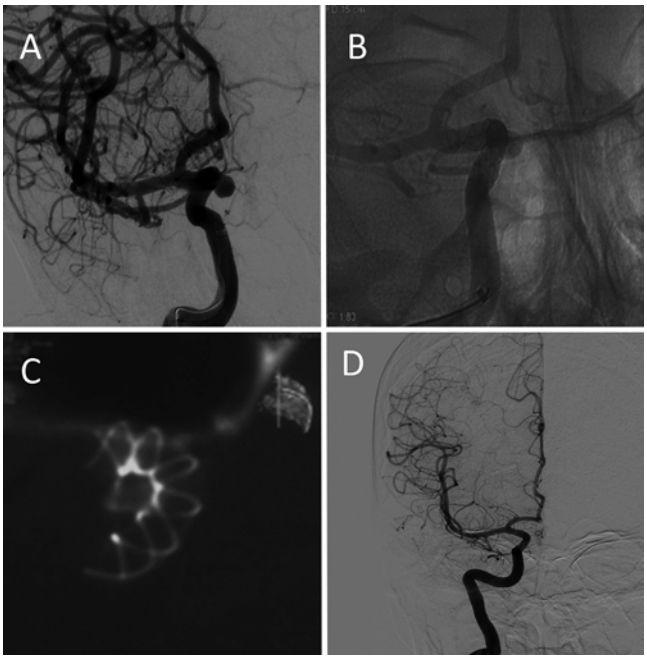

FIG. 2. A: A C6 aneurysm. **B:** Treatment with the TFD. **C:** Vaso CT (high-resolution cone-beam CT) scan showing good deployment and vessel wall application of the TFD. **D:** One-year DSA image showing complete aneurysm occlusion.

change in mRS scores at the 6-month follow-up was 0.0 ± 0.79 when compared with the baseline.

Safety Outcomes

At the 12-month follow-up, no cases of hemorrhagic stroke were observed. All strokes that occurred in this series were ischemic. The incidence of any symptomatic stroke attributed to the target aneurysms was 4.5% (9/200). In these 9 stroke cases, 2 patients experienced transient ischemic attacks and 7 patients experienced thromboembolic events. Of the 7 cases of thromboembolism, 5 patients had a symptomatic stroke but without persistent neurological deficits at the last follow-up, 1 had a persistent deficit caused by acute in-stent thrombosis, and 1 had a brainstem infarct due to subacute thrombosis that resulted in neurological death. The incidence of all-cause mortality was 1.5% (3/200). Furthermore, it was observed that 10 branches in 8 patients were occluded at the 12-month follow-up (Table 5). Specifically, 4 branches were occluded in the ophthalmic artery and 6 branches were occluded in the posterior communicating artery. One patient who experienced transient ischemic attacks had occluded branches. Supplemental Table 3 provides detailed information on the status of the covered branches. Finally, 194 of 200 (97%) patients had an mRS score of 0 or 1.

TABLE 3. Sensitivity analysis of the primary outcome

	12-Mo Occlusion Rate	95% CI
Missing FU excluded, PPS	166/210 (79.0)	72.91–84.34
Missing FU counted as complete occlusion	195/240 (81.25)	75.73–85.98
Missing FU counted as not complete occlusion	168/240 (70.0)	63.77–75.73

FU = follow-up.

TABLE 4. Correlation analysis of complete aneurysm occlusion rate (PPS)

	12-Mo Complete Occlusion Rate	95% CI
Aneurysm type		
Single	80.9% (114/141)	73.38–86.99
Tandem	75.4% (52/69)	63.51–84.95
Treatment characteristic		
TFD only	80% (136/170)	73.19–85.73
TFD & coil	75% (30/40)	58.80–87.31
Aneurysm size, mm		
<10	79.9% (135/169)	73.04–85.65
≥10	75.6% (31/41)	59.70–87.64

Discussion

The IMPACT study is the largest prospective multicenter investigation pertaining to TFDs for the treatment of intracranial aneurysms. The data reveal a commendable technical success rate of 99% (198/200) and a substantial complete occlusion rate of 79.0% (166/210). Additionally, the study reports low morbidity and mortality rates. These findings substantiate TFD as a safe and effective therapeutic modality for unruptured ICA or VA aneurysms.

TABLE 5. Secondary and safety outcomes at 12-month follow-up

	No. (%)	95% CI
Secondary outcomes		
Successful aneurysm occlusion	188/213 (88.3)	83.16–92.26
Major (>50%) in-stent stenosis	6/167 (3.6)*	1.33–7.66
Incidence of disabling stroke or neurological death associated w/ target aneurysm	2/200 (1.0)	0.12–3.57
Retreatment of target aneurysm	0	0
Retreatment of target vessel	4/200 (2.0)	0.50–5.00
Safety outcomes		
Any symptomatic stroke	9/200 (4.5)	
Thromboembolic	7/200 (3.5)	
Transient ischemic stroke	2/200 (1.0)	
Hemorrhagic stroke	0	
Covered branch occlusion	8/200 (4.0)	
All-cause mortality	3/200 (1.5)	0.31–4.32

* In total, 175 subjects underwent 12-month follow-up angiography, but the parent arteries of 8 subjects were not evaluable.

Several studies have reported the clinical outcomes of TFDs.[4–6] Zhou et al.[5] reported the preliminary experience of using TFDs for 28 large and giant aneurysms and revealed that 72.0% (18/25) of the aneurysms were completely occluded after 6 months, with procedure-related morbidity and mortality rates of 0%. Liu et al.[4] conducted the PARAT trial, a prospective randomized controlled trial on TFD, in which they compared the outcomes of large and giant aneurysms treated with TFDs (82 participants) and conventional stent-assisted coiling (62 participants). The TFD group achieved a 75.34% complete occlusion rate at 6 months, surpassing the stent-assisted coiling group's rate of 24.53%. Nonetheless, at the 1-year follow-up, the complication rates associated with the target vessel displayed slightly higher values, reaching 14.52% in the stent-assisted coiling group and 17.07% in the TFD group. However, it is worth noting that this difference did not attain statistical significance. In the IMPACT trial, we observed a complete occlusion rate of 79.0%, a 1.0% incidence of disabling stroke or neurological death associated with the target aneurysms, a 4.5% incidence of any symptomatic stroke, no occurrence of hemorrhagic stroke, and an all-cause mortality of 1.5%. Notably, the IMPACT trial exhibited significantly lower complication rates compared with the PARAT study. The variations in results between the two trials may be attributed to various factors, including the criteria for selecting the treated aneurysms. The PARAT trial solely included single large or giant aneurysms, while the IMPACT trial exhibited a more heterogeneous spectrum, including aneurysms located in the posterior circulation (14.2% of the aneurysms), tandem aneurysms (31.3%), and small aneurysms (78.8%). Additionally, the learning curve could constitute another significant factor pertaining to the safety of novel devices. Numerous studies have underscored the significance of learning curves in neurointerventional procedures.[4,7,8] It is imperative to note that the current trial was executed at centers possessing an increased level of proficiency with flow diversion techniques. Furthermore, given the diverse nature of the treated aneurysms in the IMPACT trial, the obtained findings may be more indicative of real-world clinical settings.

FDs were originally developed to enhance the treatment outcomes of large and giant wide-neck intracranial aneurysms. However, their indications have progressively expanded, and the results have been encouraging.[3] Multiple studies have investigated the efficacy and safety of FDs for small intracranial aneurysms, revealing high occlusion rates with low morbidity and mortality. The PREMIER study, a prospective multicenter investigation, aimed to assess the effectiveness of FDs for small to medium (≤ 12 mm) unruptured intracranial aneurysms.[9,10] The study's authors reported a complete occlusion rate of 81.9% (113/138) at 1 year, which increased to an overall occlusion rate of 83.3% (115/138) at the 3-year follow-up.[9,10] The combined major morbidity and mortality rate was 2.1% (3/140). Xie et al.[6] reported that in 77 intracranial aneurysms treated with TFDs, complete occlusion rates of 88.46% (size < 5 mm) and 81.82% (size 5–10 mm) were achieved at the last follow-up. In our present investigation, we noted that 78.8% (189/240) of the aneurysms were smaller than 10 mm, achieving a complete occlusion rate of 79.9% (135/169), as depicted in Table 4. This discovery further underscores the efficacy and safety of FDs for small aneurysms. Notably, flow diversion offers a simplified treatment procedure and improved long-term results, particularly for tandem small aneurysms that can be covered with a single device. In the IMPACT trial, the average device utilization per aneurysm stood at 0.86, and the complete occlusion rate for tandem aneurysms reached 75.4% (52/69). Our study provides compelling evidence that TFDs represent a safe and effective treatment strategy for these complex aneurysms.

Presently, various FDs are commercially available, with numerous prospective multicenter studies conducted on these devices. In a multicenter cohort, Wakhloo et al.[11] treated 186 aneurysms using the Surpass Device (Stryker Neurovascular). Participants with both anterior and posterior lesions were enrolled, and the majority of these lesions were < 10 mm (n = 117, 62.9%). Complete occlusion was achieved in 75% (118/158) participants at the 6-month follow-up. The permanent neurological morbidity and mortality rates in this study were 6% and 2.7%, respectively. In the study by Pierot et al.,[12] 103 aneurysms were treated using the Flow Redirection Endoluminal Device (MicroVention). Among these, the majority (68.9%) were small (< 10 mm). After 1 year, complete occlusion was achieved in 66 of 90 patients, representing 73.3% of cases, and 7 of 90 (7.8%) patients exhibited remaining neck remnants. Taschner et al.[13] reported the results of a prospective multicenter trial evaluating the Derivo embolization device from Acandis. In this investigation, 119 patients with a mean aneurysm size of 14.2 ± 16.9 mm and mean neck size of 7.7 ± 9.6 mm were enrolled. At the 18-month follow-up, the complete occlusion rate was 82% (73/89 patients). The largest prospective study to date, Diversion-p64, assessed the efficacy and safety of the p64 device in 420 patients.[14] This study revealed complete aneurysm occlusion in 287 (83.7%) patients, with a combined morbidity and mortality rate of 2.42%. In summary, the results of the IMPACT trial align closely with those of the abovementioned prospective studies, demonstrating a high complete occlusion rate and low levels of morbidity and mortality.

The choice of FD material, whether nitinol or cobalt-chromium, remains contentious. Nitinol, an alloy comprising nearly equal parts of nickel and titanium, exhibits super elasticity and shape memory. Conversely, cobalt-chromium is considerably stronger than nitinol. Some studies have suggested that cobalt-chromium FDs may be slightly more challenging to deploy, particularly in the curved segment of the arteries.[15] Nonetheless, it is worth noting that nitinol FDs may exhibit a higher rate of shortening. Janot et al.[16] documented that the utilization of FDs for distal aneurysms can lead to noticeable straightening of the parent artery, which is linked to enhanced occlusion rates. This straightening effect on the parent artery may be more pronounced with cobalt-chromium stents compared with nitinol stents. Consequently, it is essential to take into account the characteristics of various FDs when choosing suitable devices for individual lesions. Moreover, further evidence is necessary to provide guidance on stent selection.

Limitations

The primary limitations of the IMPACT trial are its single-arm design and the absence of a direct comparator. Moreover, the 12-month occlusion rates may be susceptible to misrepresentation given the lack of angiographic data for several patients. As most aneurysms (78.8%) in the study were small, the generalizability of the findings to large and giant aneurysms may be limited. However, it is essential to underscore the practicality of evaluating TFDs in real-world clinical scenarios.

Conclusions

The IMPACT trial represents the first prospective multicenter study aimed at assessing the safety and efficacy of TFDs for unruptured ICA or VA aneurysms (aneurysm neck width ≤ 20 mm). As the largest study of its kind to evaluate TFDs, the results establish a favorable safety profile and commendable aneurysm occlusion rates in real-world settings.

Acknowledgments

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Liu, Q Li, L Li, Lu, Wang, Guan, Zhao, T Li. Acquisition of data: Liu, Q Li, N Lv, L Li, L Xu, M Lv, C Huang, Lu, Xie, Wan, Wang, Guan, Zhao, Dai, Zhou, Q Huang, Y Xu, T Li. Analysis and interpretation of data: Liu, Q Li, L Li, Gu, C Huang, Duan, Wang, Guan, Zhao, Dai, Q Huang. Drafting the article: Liu, Q Li, L Li, C Huang, Wang, Zhao. Critically revising the article: Liu, Q Li, L Li, C Huang, Wang, Zhao, Y Xu, T Li. Reviewed submitted version of manuscript: Liu, Q Li, L Li, C Huang, Wang, Zhao, Zhou, Q Huang, Y Xu, T Li. Approved the final version of the manuscript on behalf of all authors: Liu. Statistical analysis: Liu, L Li, Wang, Zhao. Administrative/technical/material support: Liu, Q Li, L Li, Gu, L Xu, Mao, Zhong, Duan, Xie, Zhao, T Li. Study supervision: Liu, Q Li, L Li, Zhao, Y Xu, Miao, T Li.

Supplemental Information

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Data Availability

Data are available on reasonable request.

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