ORIGINAL RESEARCH

Clinical Study on the Management of Aortic Dissection Involving the Aortic Arch through Endovascular Isolation and *In Situ* Fenestration with Covered Stent

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ABSTRACT

Objective • This study aimed to investigate the clinical effectiveness of the SilverFlow branch stent through endovascular isolation and *in situ* fenestration (ISF) for the treatment of aortic dissection (AD) involving the aortic arch.

Methods • A total of 21 patients with AD involving the aortic arch, admitted to our hospital between September 2021 and January 2023, were selected for this prospective study. All patients underwent treatment with an endoluminal isolated ISF-covered stent, with the branch stent being the SilverFlow, developed by Shenzhen Xianjian Company. We assessed the success rate of the ISF procedure stent-related complications and compared the volumes of the true and false cavities before and after treatment. Follow-up evaluations were conducted 1, 3, and 6 months post-operation, focusing on neurological complications, mortality, and the need for secondary interventional treatment.

Results • Among the 21 AD patients with aortic arch involvement, 20 (95.23%) underwent non-emergency surgery, while 1 (4.76%) required emergency surgery due to cardiac ischemia and signs of dissection rupture. All surgeries were successfully completed. After treatment, the average volume of the true lumen significantly decreased compared to pre-treatment levels, while the volume of the false lumen significantly increased ($P < .05$). The success rate was 100%, with only one case (4.76%) experiencing type I internal leakage. There were no cases of stent displacement, distortion, or fenestration vessel occlusion. One patient (4.76%) succumbed to acute pericardial tamponade, resulting in a mortality rate of 4.76%. Another patient (4.76%) suffered from upper limb ischemia, significantly improving with antithrombotic drug treatment. No occurrences of stroke, visceral ischemia, or other complications were reported, and no secondary interventional treatments were required.

Conclusions • The application of the SilverFlow branch stent for endovascular isolation of ISF in AD cases involving the aortic arch demonstrates a high success rate, low complication and mortality rates, and significant clinical feasibility and value. (*Altern Ther Health Med.* 2023;29(8):770-775).

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INTRODUCTION

Aortic Dissection (AD) is an acute and severe cardiovascular condition resulting from the impact of high-speed and high-pressure blood flow on the aortic intima.[1] This impact leads to intimal tears, bleeding, and the formation of a dissection hematoma, resulting in the separation of various aortic wall layers and a false lumen creation.[2] Epidemiological studies have estimated the incidence of AD to be approximately 2 to 3 cases per 100 000 person-years.[1,2]

The disease primarily affects individuals aged 60 to 70 and exhibits a higher prevalence in men than in women.[3] According to the DeBakey classification, it can be categorized into three primary types: Type I and Type II correspond to Stanford Type A, which involves the ascending aorta, while Type III corresponds to Stanford Type B, limited to the descending aorta or extending into the abdominal aorta.[2]

However, AD involving the aortic arch but not the ascending aorta is classified as DeBakey type III. The primary approach to clinical treatment is minimally invasive endovascular intervention.[2] With advancements in endovascular technology and interventional devices, techniques such as the chimney technique and *in situ* fenestration (ISF) have progressively become the standard surgical procedures for patients with DeBakey type III AD.

These techniques effectively reduce the risks associated with surgical nerve injury and bleeding. These techniques are continually advancing and gaining greater refinement.[3,4]

The covered stent plays a pivotal role in *in situ* fenestration technology. It serves to isolate aortic arch lesions while maintaining the patency of the aortic arch, making it a critical component in achieving effective vascular repair.[5] However, the chimney and fenestrated stents currently available in the market, such as Gore's Vibanhen and Bard's Fluency, are imported branched stents that require further optimization to enhance the treatment's feasibility and safety.[6] In 2021, the SilverFlow branch stent, independently developed by Shenzhen First Health Company, successfully completed clinical trials and obtained approval from the National Medical Device Licensing Authority. This milestone represents a significant advancement for patients with aortic dissection involving the arch.[4-6]

In this study, our primary objective was to investigate the clinical effectiveness of the SilverFlow branch stent using endovascular isolation and ISF for the treatment of aortic dissection involving the aortic arch. Our investigation focused on several key aspects, including the success rate of the ISF procedure, stent-related complications, changes in the volumes of the true and false cavities, the evaluation of neurological complications, mortality, and the need for secondary interventional treatment. Through this study, we aimed to establish the feasibility and efficacy of this innovative stent in managing AD within the aortic arch region.

MATERIALS AND METHODS

Study Design

A cohort of twenty-one patients with AD involving the aortic arch was selected for this study. These patients were admitted to the hospital for treatment between September 2021 (the commencement of treatment) and January 2023. This cohort comprised 16 males and 5 females, with an average age of (58.41 ± 6.32) years, ranging from 35 to 77 years. Among the patients, 18 had a history of hypertension, and there were 2 cases of renal insufficiency and 1 case of cerebrovascular disease.

Inclusion and Exclusion Criteria

Inclusion criteria were as follows: (1) patients who met the diagnostic criteria for aortic dissection (AD)[7]; (2) patients who exhibited clinical symptoms, such as pain, and had confirmed aortic dissection through angiography, with the dissection involving the aortic arch; (3) patients with complete clinical imaging data; (4) patients with a preoperative false lumen lacking thrombosis; (5) patients whose family members provided informed consent.

Exclusion criteria were as follows: (1) patients with aortic intramural hematoma; (2) patients with secondary AD caused by conditions such as syphilis or trauma; (3) patients with contraindications to endovascular exclusion treatment using ISF were excluded.

These inclusion and exclusion criteria were established to ensure that the study's subjects possess specific pathological characteristics while excluding potential interfering factors. This approach enhances the reliability and validity of the research results.

Treatment Procedure

All patients received treatment with an endovascular exclusion ISF-covered stent. Specifically, we utilized the SilverFlow branched stent, independently developed by Shenzhen First Health Company. Preoperative aortic angiography was conducted to assess the location and extent of the AD tear and measure the proximal and distal aorta diameters. The appropriate aortic stent was chosen, with the proximal end expanded by 0-5% based on the anchoring zone vessel diameter and the aortic arch diameter enlarged by 0-10%.

The branch stent diameter was also determined based on the aortic arch diameter, which was enlarged by 0-10% to cover the vascular anchor zone effectively. Fenestration length was standardized at approximately 2cm, as this length was found best to encompass the anatomical range of the aortic arch, optimizing therapeutic results.

Surgical Procedure

Patient Positioning and Anesthesia. During the initial phase of the procedure, the patient was positioned in a supine manner. Following this, standard disinfection protocols were meticulously carried out. Intravenous general anesthesia was administered to ensure patient comfort and pain management throughout the procedure. This approach and anesthesia ensured a safe and controlled environment for the subsequent surgical steps.

Groin Incision and Femoral Artery Access. A transverse incision was carefully made on one side of the groin area. Following this incision, the femoral artery was carefully exposed and isolated, preparing it for further procedure. Both the proximal and distal ends of the cuff were effectively blocked to ensure a controlled surgical environment and prevent unnecessary bleeding. These steps were crucial in facilitating access to the femoral artery and ensuring a safe and successful procedure.

Aortic Artery Catheterization. The subsequent phase of the procedure involved aortic artery catheterization. This process began with carefully puncturing the femoral artery, a critical step to gain access to the vascular system. Following the femoral artery puncture, a 6F sheath and a 5F mapping catheter were skillfully introduced into the true lumen of the aortic artery with X-ray imaging guidance. This precise catheterization process allowed for the necessary access and visualization within the aortic artery, enabling accurate placement of stents.

Aortic Angiography and Tear Identification. Aortic angiography was performed to identify the location of the proximal tear. Aortic angiography provides real-time imaging of the vascular system, allowing for the visualization of any abnormalities or lesions.

Stent Placement. A carefully selected fenestrated stent with an appropriate diameter was precisely positioned to effectively cover the proximal tear of the aortic dissection, ensuring optimal coverage. The delivery system was reloaded, maintaining precision throughout the process. Additionally, a SilverFlow-covered stent system, also selected for its suitability, was placed at the posterior edge of the left subclavian artery, addressing the specific needs of the patient. In cases where a secondary tear was present in the distal part, endovascular stent placement was conducted with great care and precision. A covered stent was inserted into the branch vessel to enhance safety and effectiveness, followed by safety embolization.

Stent Morphology Evaluation. The stent's morphology was assessed using aortography to confirm the closure of the proximal tear and vascular patency.

Closure and Suturing. In the final phase of the surgical procedure, closure and suturing were undertaken. After confirming the successful completion of the stent placement, attention was turned to the access site. Specifically, the femoral artery, carefully punctured and used for catheterization, was securely sutured to prevent postoperative complications. Additionally, the inguinal incision, which had been made during the initial stages of the procedure, was carefully sutured to ensure proper wound closure and healing.

Observation Indicators

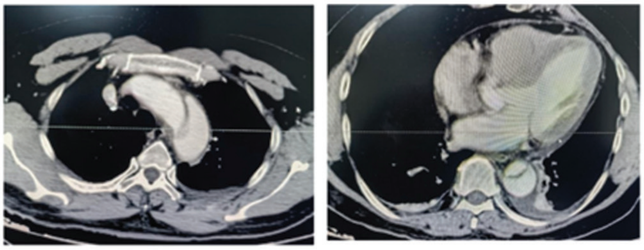
The study assessed several key observation indicators: (1) success rate of ISF operation: the success rate of the ISF procedure was counted; (2) comparison of true and false lumen volumes: changes in the volumes of the true and false lumens were compared before treatment and at the 1-month post-treatment mark; (3) stent-related complications: stent-related complications were evaluated through angiography conducted during the operation and at the 1-month post-operation point. This evaluation included an assessment of the aortic stent's morphology, the patency of the main stent graft, and the presence of complications such as endoleak, displacement, or distortion; (4) statistical outcomes: patients underwent follow-up examinations at 1, 3, and 6 months after surgery, with the follow-up period extending until January 2021. This comprehensive follow-up assessment encompassed the incidence of neurological complications, mortality, secondary intervention, and other relevant events.

These observational measures were focused on assessing the effectiveness and complications associated with AD involving the aortic arch. These outcome indicators were designed to assess surgical success and stent-related complications in patients undergoing ISF with SilverFlow branching stents. Furthermore, they aided in assessing the changes in the volumes of the true and false cavities before and after treatment.

Statistical Analysis

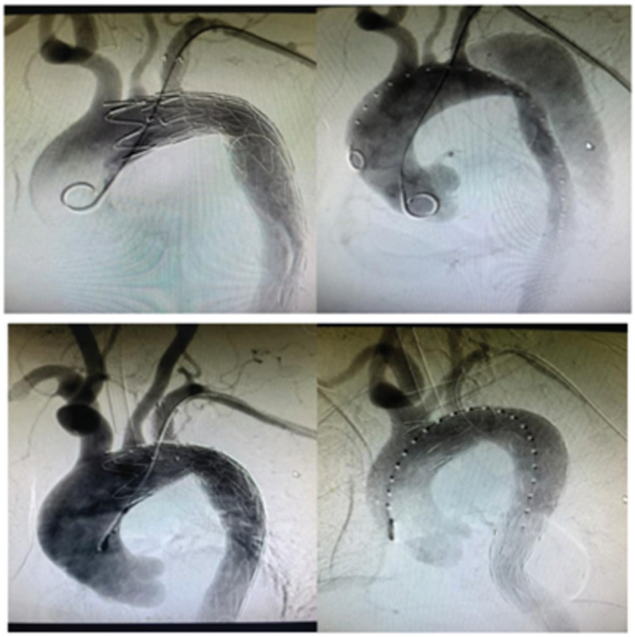
The data were analyzed using Statistical Product and Service Solutions (SPSS) 23.0 software (IBM, Armonk, NY, USA). Measurement data, such as true and false lumen volume, were subjected to a t-test and presented as ($\overline{x} \pm s$). A significance level of ($P < .05$) was considered statistically significant.

Figure 1. Preoperative results of CTA examination in AD patients



Note: Preoperative results of CTA (Computed Tomography Angiography) examination in patients with aortic dissection (AD).

Figure 2. Representation of Patients Who Have Completed Surgery



Note: Visual representation of patients who have successfully completed the surgical procedure.

RESULTS

Preoperative Examination

Preoperative angiography confirmed the presence of aortic dissection involving the aortic arch in all 21 patients, as illustrated in Figure 1.

Clinical Outcomes and Complications

Among the 21 patients with AD involving the aortic arch, 20 (95.2%) underwent endovascular isolation with ISF-coated stents once their condition stabilized. In contrast, one patient (4.76%) required emergency surgery due to dissection rupture with cardiac ischemia, and all patients successfully completed their respective treatments, resulting in a 100% success rate, as depicted in Figure 2.

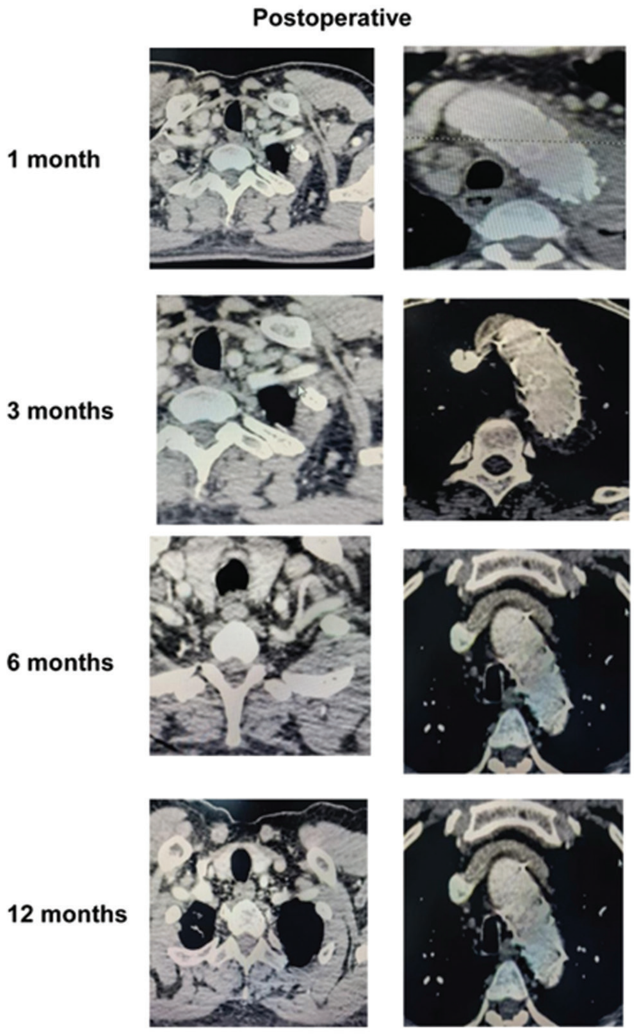
Following treatment, there was a significant increase in the average volume of the true cavity compared to before treatment, while the volume of the false cavity notably decreased ($P < .05$) (refer to Table 1). Intraoperative

Table 1. Comparison of True and False Lumen Volume Before and After Treatment ($\bar{x} \pm s$, ml)

Group	n	True Cavity Volume	False Cavity Volume
Pre-Treatment	21	148.31 ± 27.45	204.19 ± 34.58
1 Month After Treatment	21	185.43 ± 26.34	155.32 ± 27.46
t	-	3.236	3.671
P values	-	.004	.002

Note: Values are presented as means with standard deviations ($\bar{x} \pm s$, ml). True and false lumen volumes were compared before and one month after treatment. Statistical analysis was performed using the *t* test, with corresponding *P* values indicated for significant difference.

Figure 3. Follow-Up Angiography Results After Treatment



Note: Follow-up angiography results obtained after the completion of treatment. The angiography demonstrates that the blood vessels remained unobstructed with patent fenestration vessels, and no occlusion of the false lumen was observed.

angiography revealed that one patient (4.76%) experienced type I internal leakage, specifically at the proximal anchor site of the aortic stent, while the remaining patients had their stents accurately placed without any displacement or distortion.

Follow-Up and Prognosis

Among the 21 patients, one patient (4.76%) unfortunately succumbed to acute pericardial tamponade, resulting in a mortality rate of 4.76%. The remaining patients underwent follow-up examinations for a period ranging from 1 to 17 months (average follow-up duration: 9.25 ± 1.34 months). Patients who exhibited persistent symptoms related to internal leakage were monitored through periodic reexaminations, which indicated no significant changes or complications. Re-angiography conducted on other patients revealed unobstructed blood vessels with successful window openings, and no occurrences of false cavity occlusion were observed. Upper limb ischemia was noted in one case (4.76%), and notable symptom improvement was achieved through anticoagulant treatment. Importantly, no cases of stroke, visceral ischemia, or other complications were reported, and there was no need for secondary interventional therapy (refer to Figure 3).

DISCUSSION

The etiology of AD, particularly when it involves the aortic arch, remains incompletely understood. Clinical observations suggest that a combination of environmental and genetic factors may contribute to the structural degradation of the aortic media.[4-6] Traditionally, AD patients with aortic arch involvement have been treated with open surgery, which necessitates deep hypothermic circulatory arrest to facilitate aortic replacement. However, this approach has been associated with elevated mortality rates and a heightened risk of neurological complications.[6-9]

As clinical minimally invasive surgery concepts and endovascular technologies have advanced, endovascular exclusion surgery has emerged as the predominant treatment approach. This technique circumvents the need for traditional open surgery, which involves the exposure of the thoracic aorta. Consequently, it leads to a reduction in perioperative mortality and minimizes the risk of complications such as cardiac ischemia associated with aortic occlusion.[8]

However, in cases of AD involving the aortic arch, the stable implantation of a stent can be challenging due to the limited availability of a sufficient landing zone at the stent's proximal end. This limitation often complicates the execution of complete endovascular treatment strategies. Clinically, it has been proposed that the combined reconstruction of supra-arch branches may extend the length of the anchoring zone within the aortic arch.[9]

ISF, involving the reconstruction of supra-arch branches, represents a novel approach for addressing endovascular aortic arch aortic dissection. This technique utilizes an aortic-covered stent to encase the supra-arch branch vessels and employs puncture technology to reopen these covered branch vessels. In this way, it expands the proximal aortic anchoring zone, ensuring the successful execution of endovascular treatment while concurrently reconstructing the supra-arch branch vessels. However, the proximity of the stent anchoring site to the curvature of the aortic arch can lead to challenges, including the potential misfit between the branched stent and the aortic stent due to the proximal "beak" phenomenon, potentially resulting in endoleak events.[7-9]

Using branch-type covered stents can address issues such as inaccurate positioning of fenestrated stents, and it is important to recognize that different stent types exhibit varying biological characteristics. Therefore, updating and optimizing stent technology is important in reducing the risks associated with ISF procedures and enhancing surgical success rates.[10] Our study chose the SilverFlow branch stent due to its compatibility with most abdominal main stents, versatile applicability, precise positioning capability, and the potential to mitigate immediate endoleak risks.

Furthermore, this stent incorporates an interhanging weave combined with an outer twill fixation design, ensuring exceptional flexibility and consistent proximal sizing. The lineage of Silver Stream branch stents can be traced back to their initial clinical trials during the early stages of development.[10] During these initial investigations, the primary focus was on the design of the device and its initial validation for clinical use, with a strong emphasis on ensuring safety and feasibility. It is worth highlighting that these early trials may have been constrained by factors such as relatively small sample sizes and less rigorous study designs.

With the continuous advancement of technology and the accumulation of clinical experience, an increasing number of studies have shifted their focus toward assessing the long-term effectiveness and safety of Silver Stream branch stents. Some prospective studies have delved into comprehensive examinations of the long-term biocompatibility, postoperative complications, and therapeutic efficacy associated with these stents. Notably, including a V-shaped mark ensures robust connection strength, enhances visibility, and guarantees precise intraoperative positioning. Furthermore, the distal petal design enhances stent adherence to align seamlessly with aortic characteristics.

A study[11] reported on 25 patients with aortic arch disease who underwent *in situ* stent graft fenestration, achieving a technical success rate of 94.0%. Unfortunately, one patient did not survive, and three patients experienced perioperative strokes. The researchers concluded that ISF technology significantly impacts aortic arch repair. Another study[12] investigated using novel branched stents in patients with chronic aortic arch dissection undergoing endovascular repair. Their results indicated remarkably low rates for aortic reconstruction (0.15%), complications (0.035%), and mortality (0.03%), all of which are considered favorable and acceptable.

The findings of our study revealed that 20 out of 21 patients (95.23%) with AD involving the aortic arch underwent elective surgery, while 1 patient (4.76%) required emergency surgery due to indications of aortic dissection rupture resulting from cardiac ischemia. Remarkably, the emergency surgery was successfully completed. Following treatment, there was a significant reduction in the average volume of the true lumen compared to pre-treatment measurements. Conversely, the volume of the false lumen significantly increased ($P < .05$), with a remarkable overall success rate of 100%. In one case (4.76%), a type I endoleak was observed; however, the covered stents were precisely positioned without any instances of displacement or distortion.

The fenestration vessels remained patent, and no instances of false lumen occlusion were detected. Tragically, one patient died due to acute cardiac tamponade, resulting in a mortality rate of 4.76%. Additionally, one patient (4.76%) experienced upper limb ischemia, and their symptoms significantly improved following anticoagulant treatment. The application of SilverFlow branched stents proved to be both safe and effective. However, given the relatively short duration of this stent's presence in the market, a long-term follow-up is essential further to enhance our understanding of its extended clinical efficacy.

Study Limitations

Some limitations of this study should be acknowledged. First, the sample size was limited. The relatively small number of patients included in this study, 21, may have limited the statistical power and generalization of the study. Studies with larger sample sizes may be able to provide more convincing results. Second, the study was conducted in a single center, and all patients were from the same hospital, which may lead to some limitations in the applicability of the findings to other hospitals. A multi-center collaborative study may be more helpful to validate the results of this study. Finally, the follow-up time was short: the follow-up time in this study was 1, 3, and 6 months, and although early treatment effects were observed, the long-term effects and continued stability have not been fully evaluated.

In the future, extended research with larger patient cohorts, multi-center collaborations, and longer-term follow-up assessments will be instrumental in providing a more comprehensive understanding of the efficacy and safety of SilverFlow branched stents in treating aortic arch dissections. Additionally, exploring advanced stent technologies and optimizing surgical techniques may further enhance patient outcomes in this challenging clinical scenario.

CONCLUSION

In conclusion, the utilization of SilverFlow branched stents for managing aortic dissections within the aortic arch demonstrates a remarkable success rate, coupled with a low incidence of complications and mortality. These findings underscore the feasibility and clinical applicability of this innovative approach, highlighting its potential as a valuable addition to the armamentarium of treatments for aortic arch pathologies.

CONFLICT OF INTEREST

The authors have no potential conflicts of interest to report relevant to this article.

AUTHORS' CONTRIBUTIONS

XS and GL designed the study and performed the experiments, YW and DZ collected the data, XZ and PG analyzed the data, and XS prepared the manuscript. All authors read and approved the final manuscript.

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