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A Large Retrospective Study to Evaluate Utility of Zephyr Covered Stent in Transcatheter Closure of Sinus Venosus Defects

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ABSTRACT

Background: Transcatheter closure (TCC) of sinus venosus defects (SVD) using balloon-expandable covered stents is an emerging alternative to surgery. ZephyrCS (Sahajanand Laser Technologies, Gandhinagar, India) is available in long lengths to suit SVD closure. A recent hybrid design with a short uncovered end intends to prevent left innominate vein and additional high-draining pulmonary vein occlusion.

Aims: Study the procedural success, serious adverse events, stent performance parameters and need for reintervention after SVD closure.

Methods: This retrospective, single-center observational study analysed all consecutive SVD closures using ZephyrCS between January 2022 and December 2025.

Results: TCC was attempted in 100 patients with a median age of 33 years (4–73 years). Availability of long stents allowed a single-stent strategy (hybrid in 14) in 79% and elective overlapping stents only in 21%. 79 mm stent length was more frequently used. Additional stents to bail-out embolization, caudal migration, and fabric leak were required in 22%. Median stent shortening was 9%, and recoil was negligible (median 2%). Procedural success was 98%; two embolizations required surgery. 73.5% had no residual shunt at 1-year transesophageal echocardiography. At a median follow-up of 21 months (2–41 months), residual leak warranted two reinterventions. Asymptomatic intraluminal stent thrombosis was noted in 10.2%, and minor insignificant fabric leak in 11.2%.

Conclusions: ZephyrCS is safe, feasible, and effective for SVD closure, with acceptable mid-term outcomes. Long stents and hybrid design are useful for most anatomic variations. Even though minor fabric leak and intraluminal stent thrombus were not clinically significant, they need to be addressed.

1 | Introduction

Transcatheter closure (TCC) of sinus venosus defects (SVD) with balloon-expandable covered stents has become an established alternative to surgery in appropriately selected patients [1, 2]. The deployment of a long covered stent from the superior vena cava (SVC) into the right atrium (RA) effectively seals the interatrial shunt associated with SVD and facilitates the redirection of the anomalous right upper pulmonary vein (RUPV) into the left atrium (LA) behind the stent [3]. Evidence from large registries and multicentre studies supports high procedural success rates alongside low complication rates [4–7].

Long covered stents are generally preferred for SVD closure, as they facilitate complete occlusion and provide a stable anchor within the SVC to prevent stent embolization [4, 8]. However,

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limited availability of long covered stents in various countries remains a significant barrier to the widespread implementation of TCC in SVD [6]. In circumstances where long stents are unavailable, it is common practice to overlap two stents—where the second may be either covered or uncovered—to achieve the required length [3, 4, 6]. The 10Z covered Cheatham platinum stent (CCP) and G-Armor (NuMed, Hopkinton, NY), which are among the most frequently used stents in international registries, are available in lengths up to 6 and 6.3 cm, respectively [6]. Custom-manufactured extended lengths (7–10 cm) of these stents are accessible on a compassionate use basis in select countries only [6, 8]. The Optimus-CVS XXL covered stent (AndraTec, Koblenz, Germany), featuring a partially covered hybrid design, is available in 8 to 10 cm lengths and is being evaluated in the ongoing OPTIVENOUS study [9, 10]. It should be noted that both of these stent designs undergo considerable shortening up to 66%–78% when expanded to maximal diameters, and their availability is restricted to some countries.

The ZephyrCS (Sahajanand Laser Technology, Gandhinagar, India) is a balloon-expandable cobalt-chromium stent, coated with expanded polytetrafluoroethylene [11, 12]. Its architecture incorporates "C" and "S" shaped links, which enable it to expand to larger diameters while maintaining shortening < 10%. The stent is offered in both fully covered and partially covered hybrid designs, making it theoretically appropriate for SVD closure [13]. This study presents real-world data from a single centre assessing the safety, effectiveness, and overall performance of ZephyrCS in a large number of consecutive TCC procedures for SVD.

2 | Methods

This retrospective, single-centre observational study encompassed all consecutive patients who underwent TCC of SVD with ZephyrCS as the exclusive stent for initial deployment between January 2022 and December 2025. Patients who received an additional non-Zephyr stent for elective stent overlap during the initial procedure were excluded. However, cases in which a non-Zephyr stent was used subsequent to the initial deployment to bail out complications such as stent migration or fabric leak were included in the analysis. Institutional review board approval was obtained for retrospective data assessment and anonymized reporting (MMM-IEC-NCT:053/2025).

2.1 | Stent Description

ZephyrCS is a balloon-expandable stent designed to minimize shortening during expansion and has demonstrated both clinical effectiveness and safety [11]. Constructed from Cobalt–Chromium MP35N alloy, it features a semi-open 12-crown structure made with a zig-zag pattern and flexible "S" and "C" shaped poly-links to enhance trackability and reduce shortening to 91% when expanded to its maximal diameters (Figure 1). The Zephyr CS stent is covered with expanded polytetrafluoroethylene, which is abluminally secured through a sutureless sintered lamination process using heat and pressure, unlike the covered CP stent (Numed, Hopkinton, NY), where the fabric is glued at either end on two points [12]. The lamination process prevents peeling and potential slippage of the fabric from ZephyrCS. The stent is approved for clinical use under License No. MFG/MD/2019/000110 by the Central Drugs Standard Control Organisation of the Government of India. While CE approval is pending, it is approved for use in a few other countries also.

There are two stent versions (Figure 1):

- The fully covered version has struts that are 4.2 mm long and can expand to a diameter of up to 28 mm. It is available in lengths of 49, 59, 69, and 79 mm.
- The hybrid version is partially uncovered for 16 mm at one end, has 5.2 mm long struts, and can expand to a maximum diameter of 32 mm. Hybrid stents come in 80 mm and 100 mm lengths [13]. The hybrid stents became available only in the last year of the study period.

2.2 | Pre-Procedural Imaging

Contrast-enhanced computed tomography (CT) served as the primary imaging modality for pre-procedural assessment.

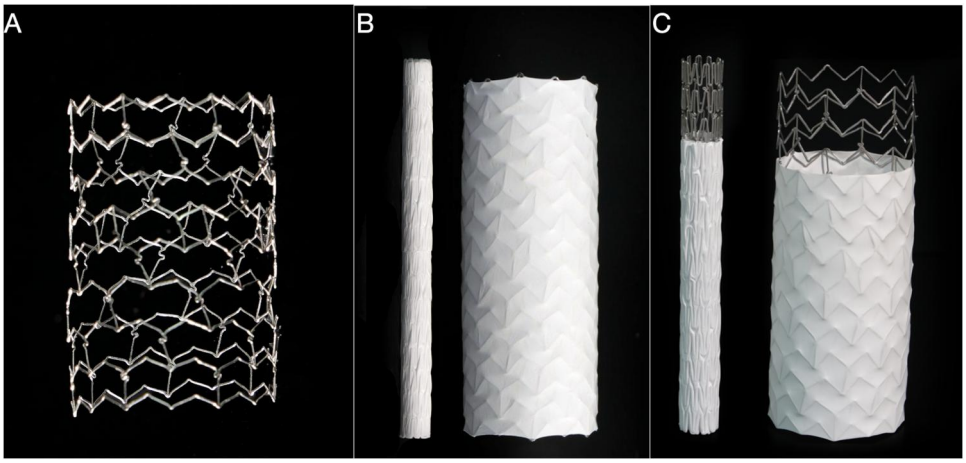


FIGURE 1 | The C and S polylinks in Zephyr uncovered stent (A) reduces stent shortening to 91% on maximal expansion. Fully covered ZephyrCS (B) and hybrid version (C) show minimal shortening on maximal expansion. [Color figure can be viewed at wileyonlinelibrary.com]

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Virtual reality was employed in a limited number of cases when available [14]. This analysis evaluated the presence of bilateral SVC, the anatomical location of the anomalous RUPV, the existence of additional high-draining right pulmonary veins, and SVC dimensions at its upper end and at the cavo-atrial junction. Echocardiography was utilized to determine the presence and severity of pulmonary hypertension, as well as to identify associated oval fossa defects.

2.3 | Balloon Interrogation

During balloon interrogation, RUPV was almost always accessed transeptally either through a patent foramen ovale, an oval fossa defect, or often by a transseptal puncture. A semi-compliant BIB or Zmed balloon (Numed Inc, Hopkinton, NY) with a diameter 4 mm larger than the SVC was inflated at the cavo-atrial junction in patients with single SVC. As the SVC was small in patients with bilateral SVC, the diameter of the balloon was selected to match the sagittal CT distance between the superior limbic edge of the SVD posteriorly and the base of the RA appendage anteriorly. RUPV angiography was performed during balloon inflation to confirm effective occlusion of the SVD and unobstructed rerouting of RUPV flows into the LA. The balloon was upsized by 2–4 mm for residual shunting and downsized by 2–4 mm if there was contrast hold-up or elevation of RUPV pressures beyond LA pressure. In patients who showed such contrast hold-up or mild elevation of RUPV pressures while demonstrating closure of the SVD, pulmonary vein protection (PVP) technique was used during subsequent stent deployment [4, 5]. Paediatric patients with a single SVC were considered eligible if the SVC could accommodate a 16 mm stent. This was not considered a limiting factor in bilateral SVC.

2.4 | TCC

To ensure stability, the covered stent should anchor 2.5 cm within the SVC and extend at least 1 cm past the caudal SVD margin. If a stent longer than 7.5 cm was required, additional covered or uncovered stents were overlapped. In cases where small, high-draining right pulmonary veins could not be redirected into the LA, an uncovered stent was overlapped cranially to maintain their drainage into the SVC. In recent times, the longer 8 and 10 cm hybrid version of ZephyrCS was preferred instead of overlapping stents [13]. The stent was crimped on the same balloon that proved successful during balloon interrogation. When RUPV angiogram showed residual flows after stent deployment, a brief transesophageal echocardiography (TEE) was done to identify incomplete apposition. It was addressed by post-dilation with a large balloon. Routine continuous intraprocedural TEE monitoring was rarely practiced as closure was primarily assessed by RUPV angiogram, unless kidney diseases precluded contrast use [15]. Intubation anaesthesia with mechanical ventilation was rarely used as continuous TEE monitoring of the entire procedure was not our routine practice. Similarly a jugular vein access for veno-venous circuit creation was also rarely used. If SVC anchor became insufficient from stent shortening or migration, another covered or uncovered stent was overlapped at the cranial end. Any associated oval fossa defects were closed using standard occluders [16]. At completion of the procedure, cine acquisition of the stent with a calibrating marker pigtail measured the diameter at either stent end as well as stent length to assess recoil and shortening percentages, respectively.

2.5 | Antithrombotic Strategy

Unfractionated heparin was used during the procedure to maintain the activated clotting time above 250 s. Initially, patients received both aspirin and clopidogrel for 6 months, then continued with aspirin alone for another 6 months. Oral anticoagulants such as warfarin or newer agents were only given to those diagnosed with atrial fibrillation. A review showed that 5% of patients in the initial group experienced silent intraluminal layered stent thrombosis [4]. As a result, the protocol was revised so that aspirin was paired with either warfarin or a new anticoagulant for the same duration. Analysis of stent thrombosis following TCC of SVD using various covered stents was reported earlier [17].

2.6 | Follow-Up Protocol

Patients were clinically assessed at 1, 6, and 12 months after the procedure, and then yearly. TEE was chosen as the main imaging technique due to its excellent spatial and temporal qualities, easy availability, quick scheduling, and reasonable cost. TEE was performed at 1 month and again at 12 months before stopping thromboprophylaxis. During follow-up, TEE evaluated for stent thrombus, fabric leaks, residual leaks from SVD edge, and assessed redirection of RUPV. For younger patients who could not undergo TEE, magnetic resonance imaging (MRI) or CT were used instead. Cobalt-chromium used in these stents provided exceptionally clear, artifact-free images on TEE and CT and simplified follow-up assessment (Figure 2).

2.7 | Statistical Analysis

The data were analysed with IBM SPSS Statistics version 25 (IBM Corp, Armonk, NY). For categorical variables, results were shown as numbers and percentages. Continuous variables were reported either as mean ± standard deviation or as median and range, depending on the data. Continuous variables were assessed with the Mann–Whitney *U* test. The relationship between stent expansion, shortening, and fabric breach was evaluated using the Pearson correlation coefficient. A p value < 0.05 (two-sided) was considered statistically significant.

3 | Results

From January 2022 to December 2025, TCC was performed with ZephyrCS in 100 patients diagnosed with SVD. Table 1 provides a summary of their demographic, clinical, and anatomical features. The median age was 33 years, and 11 patients were aged under 12 years [18]. Nearly half of the patients reported symptoms of dyspnoea. A minority presented with arrhythmias (4%) or paradoxical embolism (1%). Bilateral SVC in 24% of cases and a high-draining additional RUPV in 31% of

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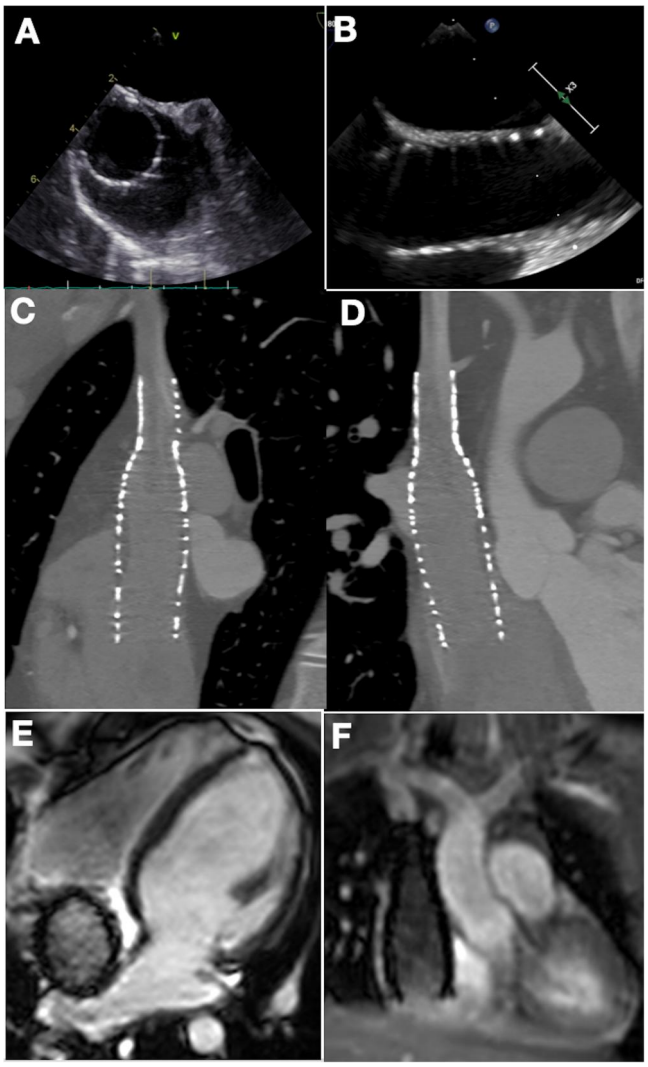


FIGURE 2 | Follow-up imaging involved transesophageal echocardiography in majority as shown in short-axis (A) and long-axis (B) views. Few patients were evaluated by computed tomography as shown in sagittal (C) and coronal (D) reconstructions or by magnetic resonance imaging as shown in axial (E) and coronal (F) images.

cases were the anatomical variations. Pulmonary hypertension was present in two-thirds of patients, typically at mild levels. CT scans were conducted in almost all cases (97%), while adjunct preprocedural TEE was used in 20%.

3.1 | Procedural Characteristics

Procedural and technical aspects are outlined in Table 2. Transseptal RUPV cannulation was performed in almost all patients utilizing septal puncture (75%), patent foramen ovale (18%), or pre-existing secundum atrial septal defect (6%). Mechanical ventilation for continuous TEE monitoring was required in 12% of cases, while a brief intraprocedural TEE was employed in 35%. Balloon interrogation with the initially chosen balloon succeeded in 73% of instances; upsizing was required in 9%, and downsizing in 18%. PVP was executed in 43% of patients.

TABLE 1 | Demographic, clinical and anatomical details.

Parameters	*N*-100 (%)
Age* in years (median, range)	33 [4–73]
Age ≤ 12 years[$]	11 [11]
Male gender[$]	49 [49]
Symptoms[$]	
Asymptomatic	46 [46]
Exertional dyspnea	52 [52]
Paradoxical embolism	1 [1]
Arrythmias	4 [4]
Weight in kilograms*	66 (13–113)
Body Surface Area in square meters*	1.73 (0.82–2.25)
Bilateral superior vena cava[$]	24 [24]
Additional high-draining pulmonary vein[$]	31 [31]
Pulmonary hypertension[$]	67 [67]
Mild	55 [55]
Moderate	8 [8]
Severe	3 [3]
Pre-procedural imaging[$]	
Transesophageal echocardiography	20 [20]
Computed tomography	97 [97]
Magnetic resonance imaging	4 [4]

Note: *Data expressed in median and range. [$]Data expressed in percentage.

3.2 | Zephyr Stent: Characteristics and Performance

A fully covered ZephyrCS was used in 86 patients, whereas the hybrid variant was utilised in 14 cases. Thanks to the availability of ZephyrCS in longer lengths, a single-stent approach was initially chosen for 79 patients; the remaining 21 patients required an elective overlap of two stents during the first deployment. In 18 cases, the main covered stent was deliberately overlapped with a cranial 49 or 59 mm uncovered stent to prevent occlusion of an additional high-draining pulmonary vein. For three patients who needed a stent longer than 79 mm, another 59 mm ZephyrCS was overlapped cranially. Among the 14 patients receiving the recently available hybrid stent, a two-wire technique was deployed in five instances, as detailed previously [13]. This strategy accurately positioned the cranial uncovered end to ensure unhindered drainage of either the additional high-draining pulmonary vein or the left innominate vein.

3.3 | Stent Lengths and Diameter of Expansion

The most commonly utilised primary covered stent measured 79 mm in length, and was implanted in 55% of patients. At the extremes of stent lengths, a 100 mm hybrid stent was deployed in one patient, while the shortest stent, measuring 49 mm, was placed in the youngest patient, who was aged 4 years and

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TABLE 2 | Procedural details.

Procedural data and stent characteristics	*N*-100 (%)
Intra procedural intubation anesthesia[$]	12 [12]
Intraprocedural transesophageal echocardiography guidance[$]	35 [35]
Left-to-right shunt ratio by Fick oximetry*	2.32 (1.5–4.0)
Right upper pulmonary vein cannulation[$]	100 (100)
After trans Septal puncture	75 [75]
Through a Patent foramen ovale	18 [18]
Pre existing Secundum ASD	6 [6]
Retrograde arterial cannulation through mitral valve	1 [1]
Successful rerouting with first chosen balloon[$]	73 [73]
Need for upsizing the balloon	9 [9]
Need for downsizing the balloon	18 [18]
Right Internal jugular vein access[$]	3 [3]
Pulmonary vein protective balloon inflation during stent deployment[$]	43 [43]
Additional oval-fossa defect device closure[$]	6 [6]
Number of stents chosen initially per case[$]	
Initial strategy to use a single covered stent	79 [79]
Single covered stent	65 [65]
Single hybrid stent	14 [14]
Initial strategy to overlap two stents	21 [21]
Overlapping covered and bare stent	18 [18]
Overlapping covered stents	3 [3]
Length of primary covered stent used[$]	*n*–100
49 mm fully covered ZephyrCS	1 [1]
59 mm fully covered ZephyrCS	16 [16]
69 mm fully covered ZephyrCS	14 [14]
79 mm fully covered ZephyrCS	55 [55]
80 Hybrid covered ZephyrCS	13 [13]
100 Hybrid covered ZephyrCS	1 [1]
Length of second overlapping stent used for initial deployment	*n*–21
Zephyr Covered 59 mm	3 (14.3)
Zephyr uncovered 49 mm	8 (38.1)
Zephyr uncovered 59 mm	9 (42.7)
Zephyr uncovered 69 mm	1 (4.8)
Additional stent to bail out embolization, migration, or fabric leak[$]	22 patients (23 stents)
Stents used for bail out (*n*–23)	
Zephyr covered	10 (43.5)
Zephyr bare	8 (34.7)
Zephyr hybrid	2 (8.7)
CP covered	2 (8.7)
Andra bare	1 (4.3)
Total stents in 100 patients –144; elective overlap [21], bail out [23][$]	
One stent	65 [65]
Two stents	27 [27]
Three stents	7 [7]
Four stents	1 [1]
Balloon diameter for the initial covered stent ($n = 100$)*	24 [12–28]
Flaring of lower end with larger balloon[$]	38 [38]
Largest balloon diameter for post-dilatation ($n = 38$)*	28 [18–30]
Maximum stent diameter achieved*	23 (14.5–36)
ZephyrCS	22.5 (14.5–30)
Zephyr Hybrid	26 [22–36]
Ratio of upper end to lower end diameter*	0.71 (0.4–1)
Stent shortening (%)*	9 [1–16]
Stent recoil (%)*	2 (0–18)
Procedural time (min)*	100 (45–240)
Fluoroscopy time (min)*	27.29 (10.8–82.1)

Note: *Data expressed in median and range. [$]Data expressed in percentages.

weighed 13 kg (Figure 3). The median balloon diameter for stent deployment was 24 mm, with a range of 12–28 mm. Post-dilation with a larger balloon at the lower stent end was performed in 38 cases. The maximum diameter achieved at the lower stent end was 30 mm for the fully covered version and 36 mm for the hybrid version.

3.4 | Stent Shortening and Recoil

Stent shortening and recoil were assessed by analysing post-procedural fluoroscopic images with the aid of a calibration marker pigtail. Precise measurements were achievable for 65 patients who received a single stent, but challenging in the rest with overlapping stents. The median stent shortening was 9% (range: 1%–16%). No correlation was observed between the final expanded stent diameter and the percentage of stent shortening (correlation coefficient: –0.19, p value: 0.27), and there was no differential shortening in cases with asymmetric expansion (Figure 4). Stent shortening was comparable between regular stents (median 9%) and hybrid stents (median 8%) with a p-value of 0.67. As deployment in SVD involved non-stenotic

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zones, significant stent recoil was not anticipated. The median stent recoil was 2% (range: 0%–18%), which was neither clinically relevant nor significant. It should be noted that the percentage recoil might be overestimated due to the absence of direct measurement of maximum stent diameter during balloon expansion.

3.5 | Procedural Outcome: Failures

Procedure was successful in 98% of cases.(Table 3) There were no additional complications in the 11 patients under 12 years of age. Stent embolization in two patients necessitating surgical retrieval contributed to procedural failures. One male aged 52-years with SVD and an additional high-draining vein received a single 80 mm hybrid ZephyrCS mounted on a 28 mm BIB balloon. RUPV angiogram after post-dilation of the lower end to 30 mm showed closure of the SVD and RUPV redirection to the LA. The open side-struts draining the additional high-draining pulmonary vein were dilated using an 8 mm balloon to optimize the flows, which probably compromised the upper SVC anchoring and subsequently led to stent embolization following guidewire and sheath removal. The second case involved a 30-year-old patient with an additional high-draining RUPV who underwent stenting with a single 79 mm ZephyrCS, positioned immediately below the additional vein using a 26 mm Zmed balloon. Although shunt closure was achieved, the SVC anchorage appeared insufficient, prompting the placement of an overlapping stabilizing 49 mm Zephyr uncovered stent. The stent assembly embolized immediately after guidewire removal. It is important to note that suture holding techniques were not adopted in this cohort [19, 20].

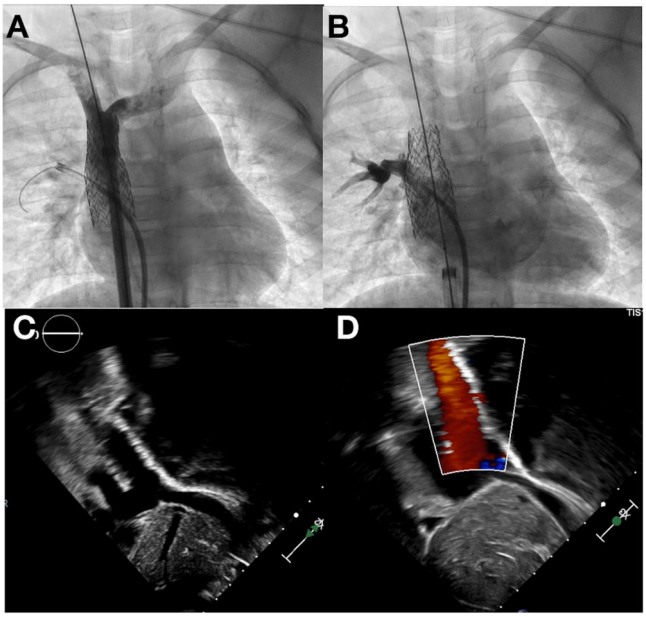


FIGURE 3 | Superior venacaval (A) and right upper pulmonary vein (B) angiogram following the shortest 49 mm ZephyrCS deployment in a 4-year-old child, the smallest patient in this study. Follow-up transthoracic echocardiogram (C) with color Doppler imaging (D) after one year demonstrates lack of residual flow and thrombus formation. [Color figure can be viewed at wileyonlinelibrary.com]

3.6 | Stent Embolization Salvaged in Catheterization Lab

After deploying a single ZephyrCS and before removal of the guidewire, three instances of stent embolizations into the RA occurred. The same balloon utilized for stent expansion was reinserted within the embolized stent and inflated to advance it cranially toward the SVC. While securing the stent at the cavoatrial junction, internal jugular access was obtained in two patients to advance a second covered stent for stabilization in the SVC. In the third patient, the embolized stent was repositioned securely by pushing it in the SVC, and an additional stabilizing stent was placed via the same femoral venous access without resorting to jugular vein puncture.

3.7 | Caudal Migration Management

A minimal caudal migration during deployment without frank embolization was observed in 15 cases. The initial approach consisted of a single ZephyrCS in 9 patients, while the remaining 6 patients with a high-draining additional vein received a combination of overlapping ZephyrCS and an uncovered stent. In these latter cases, caudal migration during deployment resulted in a residual leak through the uncovered struts of the cranially positioned bare stent. Resolution was

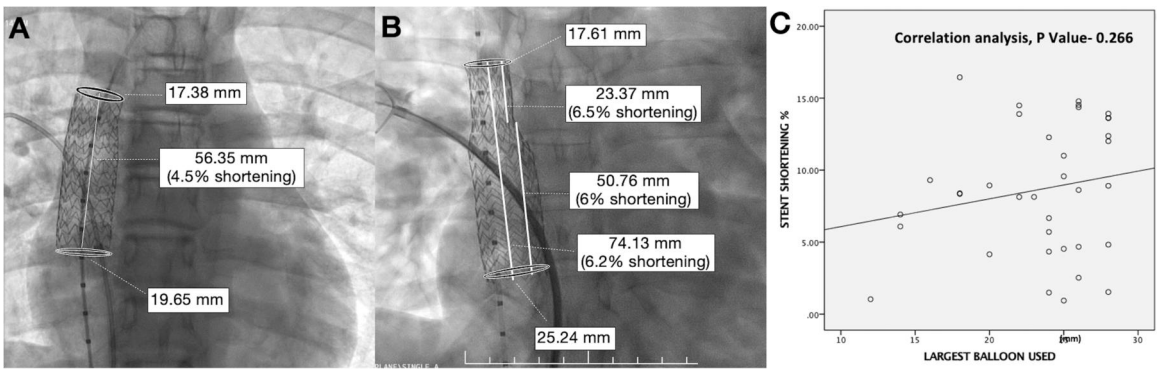


FIGURE 4 | A 59 mm long ZephyrCS deployed with a 20 mm balloon in a young patient (A) shows minimal 4.5% shortening and < 2% recoil. A 79 mm stent that showed differential expansion did not show differential shortening (B) as upper end expanded to ~18 mm shows 6.5% shortening and lower end expanded to ~25 mm shows 6% shortening. No correlation was observed between the final expanded stent diameter and the percentage of stent shortening (C).

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TABLE 3 | Procedural outcomes.

Procedural outcomes	N-100 (%)
Procedural success	98 [98]
Complications	
Embolization requiring surgery	2 [2]
Embolization managed by transcatheter means	3 [3]
Caudal migration needing additional stent	15 [15]
Left innominate vein jailing requiring recanalization	3 [3]
Major fabric breach needing additional stent	3 [3]
New onset atrial fibrillation/ supraventricular tachycardia	3 [3]
Injury of cannulated additional high-draining vein	1 [1]
Residual leak immediate post procedure (N−98)	
No	40 (40.8)
Trivial	40 (40.8)
Mild	18 (18.4)

TABLE 4 | Follow-up data.

Follow up	N-98 (%)
Follow up duration (months)*	21 [2–41]
Antithrombotic strategy	
Dual antiplatelets	55 (56.1)
Anticoagulation	43 (43.9)
Follow-up imaging modality	
Transesophageal echocardiography	82 (83.7)
Only Transthoracic echocardiography	6 (6.1)
Magnetic resonance imaging	2 [2]
Computed tomography	10 (10.2)
Residual leak at 1-month follow-up	
No	55 (57.3)
Trivial	28 (30.2)
Mild	7 (8.3)
Fabric leak (minor)	11 (11.2)
Reintervention on follow-up	2 [2]
Additional device closure for residual leak	1 [1]
Additional covered stent for multiple fabric leaks	1 [1]
Residual leak at 1 year follow-up (N−68)	
No	50 (73.5)
Trivial	16 (23.5)
Mild	2 (2.9)
Complications on follow-up	
New rhythm abnormality	0
Pulmonary venous obstruction	0
Thrombosis	10 (10.2)
Major	
Intraluminal thrombus needing thrombolysis	1 [10]
Thrombus between stent and free wall of RA	1 [10]
Minor	
Layered thrombus	8 [80]

Note: *Data expressed in median and range.

achieved by overlapping additional covered stents in all affected patients. While caudal embolization or migration occurred in 18% of the entire cohort, the incidence was not different in the age group under 12 years (2 among 11 patients). Earlier publications also reported similar outcomes between adults and children [18].

3.8 | Residual Leak from Fabric Leak

When a 79 mm ZephyrCS was used as part of a single stent deployment strategy, a small residual leak was observed on the post-deployment RUPV angiogram in three patients. A brief TEE identified the leak as originating from fabric endoleak within the stent. In these three patients, the first expansion of the stent was carried out using 25, 28, and 30 mm balloons. The fabric leak was resolved by internally overlapping another ZephyrCS stent, utilizing the same balloons.

3.9 | Total Number of Stents Used in the Study

The availability of covered stents exceeding 7 cm in length provided a notable benefit by enabling SVD closure with a single stent. As mentioned earlier, a single stent strategy was chosen for 79%, and an elective overlap of either a covered or bare stent was chosen for 21 patients. Beyond these 21 cases, an additional 23 stents were required to bail out stent embolization in three patients, stabilize caudal migration in 15 cases, and resolve fabric endoleak in three patients, as detailed above. The most frequently employed bail-out stents were fully covered ZephyrCS (43.5%), followed by Zephyr uncovered stents (34.7%) and hybrid ZephyrCS (8.7%). CCP served as a bail-out stent in 8.7% of cases, while a bare AndraXL stent (Andramed, Reutlingen, Germany) was used in one patient (4.3%). In total, 144 stents were implanted across 100 procedures. Of these, the procedure was completed using a single stent in 65 patients, two stents in 27 patients, three stents in seven patients, and four stents in one patient. Despite availability of long (79 mm and above) stents, the need for additional stents was related to the complex anatomy inherent in every SVD to provide adequate anchor for the primary covered stent.

3.10 | Follow-Up Data

Excluding two cases of embolization, immediate post-procedure imaging in 98 patients revealed complete absence of residual shunt in 40.8%, trivial shunt (< 3 mm) in 40.8%, and mild shunt (3–5 mm) in 18.4% of cases.(Table 4) All successful procedures

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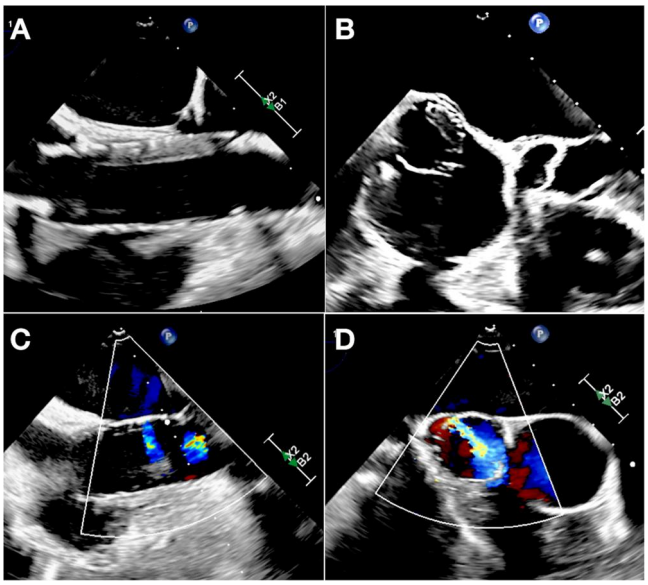


FIGURE 5 | A layered non-obstructive intraluminal stent thrombus observed on long-axis (A) and short-axis (B) views as well as small fabric microleaks on long-axis (C) and short-axis (D) during follow-up transesophageal echocardiography did not have any clinical impact, but remains to be addressed and needs follow-up on long term. [Color figure can be viewed at wileyonlinelibrary.com]

had 100% follow-up with a median duration of 21 months (range: 2–41 months). At 1-month follow-up, 57.3% demonstrated no residual shunt, while trivial and mild shunts were observed in 30.2% and 8.3% of cases, respectively. Minor fabric leaks occurred in 11 patients, all of them in the fully covered ZephyrCS (dilatable up to 28 mm), whereas no fabric leak was identified in the hybrid ZephyrCS (expandable up to 32 mm) (Figure 5). The largest balloon used for expansion was 26 mm (range 18−30 mm) in those with fabric leak and 24 mm (range 12−30 mm) in those without fabric leak. There was no correlation between the diameter of expansion and fabric leak (p value 0.26, Mann−Whitney U test). Two patients underwent reinterventions for residual shunt: one, with multiple fabric leaks in a 79 mm ZephyrCS initially expanded to 28 mm and a left-to-right shunt ratio of 1.57 on MRI, received overlapping CCP deployment after 27 months; another experienced residual shunt caused by malapposition at the caudal stent edge, requiring device closure with a 14−12 Konar MFO (Lifetech Scientific, Shenzhen, PRC). During a TEE at 1-year follow-up, there was a further reduction of the residual shunt. 73.5% of patients exhibited no residual shunt; trivial and mild shunts were present in 23.5% and 2.9% of cases, respectively. No pulmonary venous obstruction or new rhythm abnormalities were observed during follow-up.

3.11 | Stent Thrombosis

All patients received a pre-procedural single dose of aspirin and intraprocedural heparin as specified earlier. Post-interventional thromboprophylaxis consisted of dual antiplatelet therapy in 56.1% of patients, while systemic anticoagulation with Coumadin or newer agents was administered to 43.9%. Surveillance TEE revealed asymptomatic thrombus near the stent in 10 patients (10.2%), reported earlier [17]. Among these, 80% exhibited a layered intraluminal thrombus.(Figure 5) One patient developed early post-procedural systemic urosepsis and hyperpyrexia, and was found to have an asymptomatic large intraluminal stent thrombus necessitating thrombolysis due to the high thrombus burden, despite being non-obstructive. At 3-year follow-up, anticoagulation resulted in a marked reduction of thrombus burden as evidenced on TEE. Another patient demonstrated thrombus at the caudal distal edge and adjacent free wall of the RA, which resolved significantly with Coumadin therapy. Notably, none of these cases of thrombosis were associated with systemic or pulmonary thromboembolism.

4 | Discussion

This extensive single-center study indicates that SVD closure using the ZephyrCS is linked to high procedural success rates and manageable complication profiles. The device's broad range of available lengths with options up to 100 mm, minimal expansion-related shortening, and capacity for dilation to large diameters contributed to successful outcomes across diverse anatomical presentations.

4.1 | Benefit of Availability of Long Stents

A primary limitation of TCC for SVD is stent embolization, which often arises from insufficient anchoring due to short stent lengths. Stabilization techniques include the deployment of an initial anchoring stent or utilization of a suture control method [6, 8, 19]. The adoption of the long ZephyrCS demonstrated that a single-stent strategy was feasible in 79% of cases, compared to 49.1% reported in the international registry [6]. Elective two-stent overlap was predominantly necessary for patients with additional high-draining pulmonary veins, where an uncovered stent facilitated drainage through the side-struts into the SVC. This challenge has been partially mitigated by the recent introduction of the hybrid ZephyrCS variant [13]. Stent embolization resulted in a 2% procedural failure rate following ZephyrCS placement, compared to 2.6% in the international registry [6]. Employing a single-stent approach, rather than multiple stents, decreases procedural complexity, duration, and associated costs.

4.2 | Capability to Dilation to Large Diameters

Although the fully covered and hybrid versions of ZephyrCS were recommended for dilation up to maximum diameters of 25 and 32 mm, respectively, clinical practice had permitted expansion to even larger sizes. When assessing the maximal stent dimensions achieved following final expansion, the median diameter for the fully covered version and hybrid version was 22.5 and 26 mm respectively. Furthermore, 32.6% (28 out of 86) of the fully covered ZephyrCS were expanded beyond 25 mm, and 7.1% (1 out of 14) of the hybrid stents were expanded beyond 32 mm.

4.3 | Stent Shortening on Full Expansion

Stent shortening during expansion is particularly notable in closed-cell design stents such as CCP, while hybrid models

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incorporating both closed and open cells like Optimus CVS demonstrate less shortening [6]. According to stent shortening charts, CCP shortens to 66% and Optimus CVS to 78% when dilated to their maximum dimensions, making this a critical consideration during stent selection. Differential shortening resulting from non-uniform expansion at the cranial and caudal ends especially in bilateral SVC further complicates decisions regarding appropriate stent length [8, 21]. ZephyrCS exhibited a median shortening of 9%, even when dilated up to 30 mm. This shortening was independent of the final diameter, due to the distinctive "C" and "S" polylinks, which maintain near-uniform stent length (Figure 4). A predictable and minimal shortening is advantageous for TCC procedures in SVD cases.

4.4 | Major Procedural Complications

Embolization occurred with one fully covered version and one hybrid version, resulting in two procedural failures. The side-strut dilation of the hybrid stent might have contributed to instability of the SVC anchor in the latter instance; however, the fully covered stent with small SVC anchor embolized despite the subsequent placement of an overlapping stabilizing uncovered stent. Similarly, no definitive stent-related cause was identified in the three embolizations that were successfully managed intraprocedurally in the catheterization laboratory by introducing overlapping stents. The absence of robust anchorage to the walls of an expansile SVC represents a significant challenge for this technique. Differential dimensions between the upper and lower ends propel the expanding stent-balloon assembly caudally, a phenomenon potentially mitigated through suture control and the use of long introducer sheaths to counteract balloon drift [19, 20].

4.5 | Fabric Integrity of Zephyr Covered Stents

The closure of left-to-right shunt in SVD is fundamentally dependent on the fabric integrity of the covered stent [22]. A significant fabric leak during SVD closure manifests immediately on RUPV angiogram or intraprocedural TEE as a residual shunt; conversely, similar leaks in covered stents used for coarctation or conduit stenosis may remain undetected unless accompanied by significant vascular injury. In three instances, substantial fabric disruption following expansion to 25–30 mm was promptly identified and managed intraprocedurally with additional stenting. Comparable issues have been previously documented in other covered stents used in SVD closure [22]. Expansion beyond the recommended diameter could be responsible for these major fabric leaks. However, minor leaks observed on follow-up surveillance TEE in 11 patients showed no correlation with balloon diameter. Micropores ranging from 9 to 65 microns are known to be present in expanded polytetrafluoroethylene fabric [23, 24]. Future investigations may explore the impact of micropore stretching or the injury to the fabric by mechanical crimpers as contributing factors. While the fabric is affixed at both ends of the stent in CCP, cobalt-chromium stents such as ZephyrCS utilize heat and pressure to laminate the fabric onto the stent struts, representing a distinctly different mechanism [12]. While a fabric leak in a CCP may be long and extensive from peeling off, similar leaks in laminated ZephyrCS may be small and multiple from micropores.

4.6 | Thrombus in Covered Stents

Thrombus detection occurred in 10.2% of cases, which is notably higher than previously reported rates [17]. This increased incidence may stem from rigorous follow-up assessments using surveillance TEE, the most sensitive investigation to detect these thrombi. Even with optimal MRI methods, such as T2-weighted turbo spin echo sequences, substantial artifacts caused by metallic stents obscure intraluminal views, making it harder to identify layered thrombus [25]. Platinum-iridium stents like CCP produce significant metal-blooming artifacts on CT scans, further hindering intraluminal observation. In contrast, TEE images are largely free from these artifacts and offer superior spatial and temporal resolution. Analyses from our centre, following a consistent protocol, indicated a higher thrombus rate with ZephyrCS (10.2%) compared to 2.2% with CCP and 4.8% with covered Andra stents, although these differences were not statistically significant. Enhanced visualization of the stent's luminal surface by both TEE and CT after ZephyrCS placement may help detect even thin-layered thrombus [17]. However, the possible impact of stent design, including abluminal fabric lamination, on thrombus formation cannot be disregarded.

5 | Limitations

This was a retrospective, single-center study without a comparator group. Follow-up duration was mid-term, and longer-term outcomes remain to be established.

6 | Conclusions

The ZephyrCS represents a secure and effective solution for TCC of SVD, demonstrating strong procedural performance and promising mid-term results. The provision of stents with extended lengths and hybrid designs facilitates the use of a single stent across diverse morphologies, including those associated with additional high-draining PV and short SVC length. In clinical practice, stent shortening upon maximal expansion proved to be minimal. However, minor fabric leakage and layered thrombus remain important issues that require attention. A larger, multicenter prospective study with extended follow-up is recommended.

Disclosure

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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