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Endovascular Stent Provides More Effective Early Relief of SVC Obstruction Compared to Balloon Angioplasty

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Abstract

Objective—To determine whether superior vena cava (SVC) stent implantation is superior to balloon angioplasty for relieving SVC stenosis.

Background—SVC stent and balloon dilation have been used as treatment for SVC stenosis. Although safe and effective, outcome data comparing the two methods are limited.

Methods—A Pediatric Cardiac Care Consortium review identified SVC stenosis. Patients who required SVC intervention were divided into two subgroups—balloon dilation (Group A) and stent implantation (Group B). Logistic regression and the log-rank test were used to test the need for re-intervention within 6 months after the initial procedure.

Results—SVC intervention was performed on 210/637 patients with SVC stenosis (33%). There were 108/210 (51%) patients with balloon dilation (Group A) and 102/210 (49%) with stent implantation (Group B). Re-intervention within 6 months of the initial intervention was more common in Group A compared to Group B [Group A = 31/40 (77.5%); Group B = 5/22 (22.7%)]. The odds-ratio for re-intervention within 6 months of the initial procedure for balloon vs. stent, is 7.3 [95% CI: (2.91, 22.3), $P < 0.0001$]. In addition, during the first 6 months after an intervention for SVC stenosis the proportion of patients with stent implantation that remained free of re-intervention was significantly higher than after balloon angioplasty (log-rank test, $P < 0.0001$). Neither age nor weight was significantly associated with the need for re-intervention.

Conclusions—SVC stent implantation is more effective than angioplasty in relief of SVC obstruction. Weight and age are not risk factors for early re-intervention.

Keywords

SVC stenosis; stent; balloon angioplasty; re-intervention

INTRODUCTION

Superior vena cava (SVC) stenosis can be a significant complication in patients undergoing cardiac operations. Patients after cavo-pulmonary anastomosis, atrial switch operation, partial anomalous pulmonary venous return surgery, and heart transplantation are at higher risk for SVC stenosis [1–3]. Treatment options for SVC stenosis include surgical relief or catheter-based interventions, including balloon dilation or endovascular stent implantation. While both methods have been shown to be safe and effective [4–7], little data exist comparing the effectiveness of these percutaneous treatment options. The aim of this study is to determine whether SVC stent implantation is superior to balloon angioplasty for relieving SVC stenosis.

MATERIALS AND METHODS

This is a retrospective cohort study using the Pediatric Cardiac Care Consortium, a multi-institutional registry collecting data on interventions for pediatric and adult patients with congenital or pediatric onset heart disease. De-identified data were collected on patients who had SVC stenosis between January 1982 and December 2007. Because of the nature of the study, it was exempted from the University of Minnesota institutional review board approval. Patients who required endovascular SVC intervention were identified and divided into two groups depending on whether the initial intervention was balloon dilation (Group A) or stent implantation (Group B). Fisher's exact and Chi-square tests were used to test whether treatment type was independent of re-intervention within 6 months. Logistic regression and the log-rank test were used to test the association between the baseline procedure and needing re-intervention within 6 months and for comparing Kaplan–Meier intervention-free curves between baseline treatments, respectively.

RESULTS

Among 137,655 patients in the PCCC registry, a total of 637 patients were identified with SVC stenosis (0.46%). Of the 637 patients with SVC stenosis, a total of 210 (33%) patients needed intervention. The age range was 18 days to 43.9 years (mean 11.2 years, median 8.1 years). The weight ranged from 2.3 kg to 106 kg (mean 33.4 kg, median 23 kg). Of the 210 patients undergoing SVC intervention, there were 108 (51%) in Group A and 102 (49%) in Group B. There was a difference in the age of the patients in each group. The mean age at the initial procedure was 9.4 ± 9 years in Group A and was 13 ± 11.5 years in Group B ($P = 0.04$). There was no significant difference in patient mean weight (Group A = 30.7 ± 26 kg; Group B = 30.7 ± 26 kg; $P = 0.113$) (Table I).

Overall re-intervention was more common in the balloon group (Group A = 40/108; 37%), compared to the stent group (Group B = 22/102; 21%) ($P = 0.0141$). The timing of re-intervention was evaluated and showed that re-intervention within the 6 months of the initial intervention was also more common in the balloon group (Group A = 31/108; 29%) than in the stent group (Group B = 5/102; 5%) ($P < 0.0001$). Most of the repeat interventions in Group A were performed within 6 months of the initial intervention (31/40; 77.5%). By

comparison, fewer of the repeat interventions occurred within 6 months of initial intervention in Group B (5/22; 23%) (Fig. 1).

Using logistic regression analysis and after controlling for weight and age, the odds-ratio for re-intervention within 6 months of the initial procedure for balloon vs. stent is highly significant at 7.3 [95% CI: (2.91, 22.3), $P < 0.0001$]. In addition, during the first 6 months after an intervention for SVC stenosis, freedom from re-intervention was significantly higher after stenting than after balloon angioplasty (log-rank test, $P < 0.0001$). Neither age [OR = 1; 95% CI: (1.0–1.0); $P = 0.59$] nor weight [OR = 1; 95% CI: (1.01–1.04); $P = 0.78$] at the initial intervention was significantly associated with the need for re-intervention (Fig. 2).

Review of the Kaplan–Meier plots demonstrates that most of the difference between the two groups occurs within the first week after the initial procedure. A chart review of these patients showed that the majority of the balloon patients in Group A that required early re-intervention had inadequate immediate relief of the SVC obstruction and proceeded to SVC stent implantation immediately (Figs. 2 and 3). After the first week, the rate of ongoing need for re-intervention is similar in Group A (9/77; 12%) and Group B (17/97; 18%) ($P = 0.2834$) (Fig. 1).

Major complications and deaths were recorded in each group and were too rare to allow for statistical evaluation (Table I). Major complications included balloon rupture, device embolization, excessive blood loss, vascular rupture, and vascular damage. The incidence of major complications with balloon dilation was 4/108 (4%) and with stent implantation 3/102 (3%). Only one patient in the balloon group needed surgical repair of the SVC 12 days after balloon angioplasty and one patient in the stent group needed surgical repair of SVC 32 days after stent implantation. Mortality rate within one month of the procedure date was 2/108 (1.9%) in Group A and 1/102 (1%) in Group B.

DISCUSSION

The incidence of SVC stenosis is low after pediatric cardiac surgery in the PCCC database. The majority of these post-operative patients have undergone cavo-pulmonary anastomosis, partial anomalous pulmonary venous return repair, atrial switch, or cardiac transplant (Table II). Although relatively rare, hemodynamically significant obstruction can lead to SVC syndrome which carries a significant morbidity for these patients [2]. Symptomatic SVC obstruction may cause swelling and cyanosis of head and upper limbs, headache, cerebral venous hypertension, syncope, cough, and airway obstruction. Occasionally it can result in protein losing enteropathy, pleural, and pericardial effusion from the retrograde congestion on the thoracic duct.

Catheterization-based treatment for SVC stenosis has been described, utilizing either balloon dilation or stent implantation of the SVC [4–10]. Both methods have been shown to be safe and effective. Rocchini et al. were the first to report the use of balloon dilation for SVC stenosis in a child after multiple surgeries for total anomalous pulmonary venous return (TAPVR) [1]. Balloon dilation has been shown to be useful in patients with SVC obstruction

in different studies [3,7,11]. However, suboptimal results and recurrent venous stenosis remain an issue [5], often requiring future stent implantation [12].

For branch pulmonary arterial narrowing, stent placement was shown to be more effective compared to balloon dilation with regard to pressure gradient reduction and diameter increase [13]. However, arterial response to balloon dilation may be different than venous response, both in terms of effectiveness and risk for complications. Several case series and small studies have shown that stent placement for SVC stenosis is safe and effective [4,6,8,9,14,15]; however, there are limited studies comparing the two methods for treating SVC stenosis.

Tzifa et al. showed in their study which included less number of patients (63 patients) that there was no difference in freedom from re-intervention between balloon dilation and stent implantation for SVC obstruction on follow-up (1 day to 16 years). On the other hand, older patients (>5 years old at the initial procedure) and patients with history of cardiac surgery have longer freedom from re-intervention [2].

In our study, Group A (balloon) required significantly more re-interventions compared to Group B (stent) in the first 6 months after the initial procedure and most of re-interventions occurred within the first week after the initial intervention. One possibility to explain this significant difference could be related to the compliant SVC lesions which make it less likely to tear and remodel. Stent implantation for SVC stenosis has the advantage of being able to overcome the elastic recoil seen after balloon angioplasty with more satisfactory results. Although our assumption was for more re-intervention for smaller patients, we found that neither age nor weight at time of initial intervention was significantly associated with the need for re-intervention.

Jayakumar et al. contributed the causes of SVC obstruction at sites of surgical anastomosis to several factors including mismatch in vessel size, intimal hyperplasia, constriction by sutures, thrombosis, and strictures formation [12].

One might postulate that patients in the non-cardiac surgical group would be more likely to have SVC obstruction from external compression and, therefore, might be more likely to have failure of complete relief of the obstruction by balloon alone. This may lead to an overall increase in re-interventions in the Group A. For that reason, we looked specifically at non-cardiac surgical group to see whether this leads to bias towards stenting. Although the numbers were small, no difference was observed in early (within 6 months) re-intervention between the balloon (0/16) and stent (0/16) groups in the non-cardiac surgery patients.

From a histopathological stand point, arterial angioplasty on animals suggested that intimal splitting with extending the tear to the media which will lead to open position healing process is necessary for successful angioplasty [16,17]. Nonetheless, venous vessels have limited media and successful balloon angioplasty may be explained by either open position healing of a torn thickened intima or atrial myocardial wall [5]. Rocchini et al. indicated that intimal splitting and endothelial desquamation is required for successful balloon angioplasty of the SVC stenosis [1]. However, this may not be the process that is involved in postoperative suture line in a vein. Perhaps this may explain why balloon alone had a higher

rate of early failure may result in a greater need for repeat interventions than in stent patients.

O’Laughlin et al. found that balloon-expandable intravascular stents were very effective in treating vascular stenosis with good lasting patency at medium-term follow up (3–27 months, mean 11 months). Nonetheless the average weight for the venous stenosis group was 14.3 years suggesting an old age group. This explains the limited re-intervention since most of re-intervention are usually on small kids and related to somatic growth [6]

Stanfill et al. reported that stent implantation was safe and effective in infants, but required serial dilation to keep up with somatic growth. They recommended the use of an adult diameter potential stents for patients not requiring a future surgery and to only consider small to medium size stents for palliation and for patients who will need a future surgery [18]. Our data support that stent patients have early freedom from re-intervention, but a need for later re-interventions, beyond 6 months. Our data showed that of the 17 stent patients that required re-intervention after 6 months, 14 (82%) were equal or less than 7 years old. These data support that somatic growth in pediatric patients likely accounts for the need for later re-interventions. Ongoing development of biodegradable stents could, perhaps, provide an effective means of alleviating SVC obstruction, without requiring late repeat interventions.

In our study, there was no statistical significance difference in the need for re-intervention beyond 6 months and both groups had a close rate of re-intervention beyond this time point. There was also no significant difference in the rate of major complications and deaths, which were very low for both methods.

The Pediatric Cardiac Care Consortium (PCCC) has the advantage of being one of the oldest and largest databases for surgical and catheter-based interventions for pediatric heart disease. This allowed us to report perhaps the largest number of subjects comparing balloon and stent interventions for SVC stenosis. However, the PCCC database does have some limitations. Our study limitations include the retrospective nature of the study and the limited dataset nature of the PCCC registry that does not contain information about the indications for initial procedure or re-intervention, nor the procedural details. Since all patient diagnoses are entered into the database, regardless of the type of surgical or catheter procedure being performed, we identified 637 patients with SVC stenosis as a diagnosis, but we do not have information as to why only 210 patients underwent SVC intervention, nor what indications were used by centers when deciding whether or not the identified SVC obstruction deserved intervention. Since it is possible that some patients may have an initial procedure performed at a center that does not participate in this database who then had the balloon or stent procedure at a PCCC center, we could not be certain of the timing of the SVC intervention after initial surgery in all patients. In addition, the long study time period and multi-institutional approach introduces confounding variables such as changing interventional techniques.

CONCLUSION

Our study reveals that SVC stent implantation is more effective than SVC balloon dilation in treating SVC stenosis with significantly better 6-month freedom from re-intervention. Beyond 6-months, ongoing rates of re-intervention are comparable between both groups. Weight and age are not risk factors for early re-intervention.

Late re-intervention in the stent patients mostly related to somatic growth of these patients.

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Fig. 1. Distribution of patients with SVC stenosis. *(Freedom from intervention within 6 months), °(Intervention before 6 months), and ~ (Intervention after 6 months).

Fig. 2.

Kaplan–Meier plot for time to re-intervention for SVC stenosis within 6 months after the first procedure. The proportion of re-intervention free patients is greater for stent group using the log-rank test ($P < 0.0001$).

Fig. 3. Kaplan–Meier plot for time to re-intervention for SVC stenosis comparing the stent group to the balloon group. The proportion of re-intervention free patients is greater for stent group using the log-rank test ($P = 0.0046$).

TABLE I

Patient Characteristics and Outcomes of Groups A (Balloon) and B (Stent)

	Group A (balloon)	Group B (stent)	P-value
Patients (<i>n</i>)	108 (51%)	102 (49%)	
Age ^a : mean ± SD (median) (years)	9.4 ± 9 (6.6)	13 ± 11.5 (11.5)	0.04*
Weight ^a : mean ± SD (median) (kg)	30.7 ± 26 (18.9)	36.3 ± 26.7 (32.1)	0.113
Re-intervention within 6 months	31 (29%)	5 (5%)	<0.0001*
Previous cardiac surgery	92 (85%)	86 (84%)	NS
High risk surgery	70 (64%)	76 (74%)	NS
Complications	4 (4%)	3 (3%)	NS
Mortality	1 (1%)	2 (1.9%)	NS

^a At the initial procedure.

TABLE II

High Risk Surgeries for SVC Stenosis in Groups A (Balloon) and B (Stent)

	Group A (balloon)	Group B (stent)
Cardiac transplant	6 (5.6%)	17 (16.7%)
Cavo-pulmonary anastomosis	24 (22.2%)	11 (10.8%)
PAPVR repair	11 (10.2%)	10 (9.8%)
Atrial switch procedures	29 (26.9%)	38 (37.3%)
Other cardiac operation	22 (20.4%)	10 (9.8%)
No cardiac surgery	16 (14.8%)	16 (15.7%)