



## Research Brief

# Incidence, predictors, and gradation of upper extremity venous obstruction after transvenous pacemaker implantation

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## 1. Introduction

The economic costs of implanting a leadless pacemaker have to be contrasted with the incidence of management of the occlusion of the venous channels. We therefore aimed to review the prevalence of venous occlusion at follow-up post permanent pacing device implantation in a cohort of Indian patients at a tertiary cardiac care referral center.

## 2. Material and methods

### 2.1. Study population

Consecutive patients implanted with permanent pacing devices implanted at Sri Jayadeva Institute of Cardiac Sciences and Research between July 2011 and March 2012 were reviewed on follow-up. All patients without a known contrast or iodine allergy, without history of venous stenosis or venoplasty performed at device implantation with a normal renal function, and no previous clinical evidence of venous occlusion were included for participation.

Epidemiologic data and prescription information were collected for analysis in addition to details on the pacemaker. The site of venous access was reviewed using implantation records, and particular note was made of any attempts at cephalic vein cut-down.

### 2.2. Evaluation of stenosis

Informed consent was taken after explaining the risks of contrast dye allergy. A detailed history regarding the use of the arm ipsilateral to the site of the lead implantation was noted. A detailed physical examination was performed noting any dilated venous channels over the precordium and chest. An upper limb venogram using 15 ml of undiluted iohexol (diatrizoate) per view on the same side as the device implant was performed, and images in RAO 60° and LAO 30° were collected. A 6 F pigtail catheter was placed on the chest, parallel to the anticipated course of the vein used as a fluoroscopic measurement reference.

Analysis of the venogram was performed offline using semi-automated quantitative analysis methods and digital calipers on the Philips Fluoroscopy suite. A unique classification system was used for the grading: grade 1, <60% stenosis; grade 2, >60% stenosis, but not completely occluded; and grade 3, complete occlusion. The minimum diameter of the vein was measured at the site of stenosis and marked for comparison to the size of the pigtail to estimate the venous caliber.

Abbreviations: SJICSR, Sri Jayadeva Institute of Cardiac Sciences and Research.  
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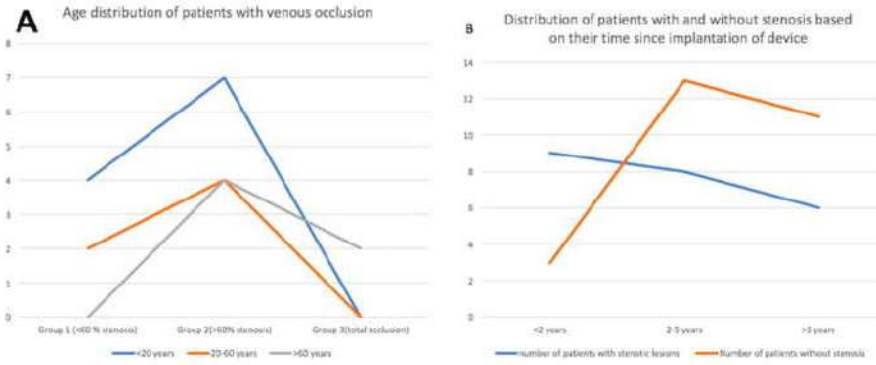
### 2.3. Statistical methods

Chi-square/Fisher exact test was used to assess the significance of differences between categorical variables between two or more groups. Multivariate analysis was performed on the variables to analyze their contribution to the venous occlusion.

### 3. Results

#### 3.1. Study population

During the course of this study, a total of 50 patients were selected. Mean age of patients was  $55.9 \pm 14.4$  years. Twenty-eight



Parameter	Stenosis		P value
	Non-Significant (n=33)	Significant (n=17)	
<b>Number of leads</b>			
1			0.78
>1	20(60.6%) 13(39.4%)	11(64.7%) 6(35.3%)	
<b>Type of leads</b>			0.24
Polyurethane	29(87.9%)	12(70.6%)	
Poly+silicon	3(9.1%)	4(23.5%)	
Silicon	1(3%)	1(5.9%)	
<b>Venous access</b>			0.84
Subclavian/Cephalic	1(3.1%)	-	
Subclavian	14(42.4%)	6(35.3%)	
<b>Ejection Fraction</b>			0.01
Normal	32(96.9%)	12(70.6%)	
Mild LVD	1(3.1%)	5(29.4%)	

**Fig. 1.** (A) Distribution of baseline characters in patients with venous occlusion: (a) age in years; (b) time post implantation. (B) Device characteristics in patients with and without occlusion. LVD, left ventricular dysfunction.

(56%) pacemakers were implanted in males. Single chamber pacemakers ( $n = 33$ ; 66%) were the most common pacemakers implanted followed by dual chamber pacemakers ( $n = 17$ ; 34%). The mean time post pacemaker implantation that these patients were evaluated with a venogram was  $4.1 \pm 4$  years, and the mean time post pacemaker implantation that they were followed-up was  $4.3 \pm 4.1$  years.

None of the patients had atrial fibrillation, and six patients (12%) had left ventricular (LV) dysfunction (mean ejection fraction (EF) =  $31 \pm 5\%$ ). There were 15 (30%) patients on either anticoagulant (7 patients; 14%) or antiplatelet (8 patients; 16%) drugs.

### 3.2. Findings on venography

Cephalic vein was used for pacemaker implantation in 30 (60%) patients and the subclavian in 20 (40%) patients. Lead placement using both the veins was noted in one patient (2%). Single lead within the venous circulation was present in 31 (62%) patients, while two leads were used in the rest of the patients. In most patients, polyurethane-coated leads were used ( $n = 41$ , 82%), whereas silicon-coated lead was used in only two (4%) of these patients, while a combination of polyurethane and silicon leads was used in seven (14%) patients.

Twenty-seven (58%) patients had no stenosis on the venogram, six (12%) patients had insignificant stenosis (grade 1) (<60%), while 15 (30%) patients had significant venous obstruction (grade 2) (>60%). Two (4%) patients had complete occlusion of the ipsilateral subclavian vein (grade 3).

All the patients were asymptomatic for any symptoms related to venous obstruction. No dilated veins were present over the chest wall except for the two (4%) patients with complete venous obstruction. The stenotic segment was at the junction of the subclavian vein with the internal jugular vein (15 patients; 30%). The distribution of the sites of obstruction is as shown in Fig. 1. Multiple sequential stenotic sites were not seen. The site of grade 3 occlusion was within the proximal subclavian vein. It was accompanied by sites of extensive collateralization with dilated veins over the chest wall.

### 3.3. Associations of venous stenosis with multivariate analysis

Patients aged >50 years had an increased incidence of venous stenosis compared with those aged <50 years [ $n = 15$  vs 2,  $p$  value = 0.03; confidence interval (CI) = 0.88–0.93]. There was significant difference in the timing of the venogram post implantation in those patients with stenosis compared with those without stenosis (2 years;  $n = 9$ ,  $p$  value = 0.013; CI = 0.91–0.96). There was no difference in the co-morbidities between patients having venous stenosis and those without venous stenosis, including the body mass index, 5/6 (83%) patients with LV dysfunction had venous stenosis. The site of venous access did not contribute to development of venous stenosis.

## 4. Discussion

Significant venous stenosis was seen in 34% of patients which parallels the findings seen in the earlier short-term (6–12 month post permanent pacemaker implantation (PPI)) and long-term follow-up studies (44 months post PPI).<sup>1–3</sup>

None of the traditional risk factors for venous thrombosis contributed to stenosis. All venous occlusion occurred within 2 years after the implantation of the device on par with study of Korkeila et al.<sup>7</sup> suggestive of perhaps an increased fibrotic response in some patients. Therefore, ongoing vigilance may have to be exerted in older patients undergoing implants especially in their initial follow-up periods given that there is independent prognostic significance of age >50 years. This hypothesis may be aided by our observation that decreased EF was also associated significantly with the incidence of venous occlusion in our study ( $p$  value = 0.014; CI = 0.82–0.89) and in a study performed by Da Costa et al.<sup>6,7,8,9,10</sup> Interestingly, the number of leads within the vein was not found statistically related to causation of pathology.<sup>3–6</sup> This counter-intuitive finding may perhaps be explained by the fact that the mean follow-up time was variable ( $8.09 \pm 4.4$  years vs 24 months vs 6 months). Lead composition as in other studies remains non-contributory to venous occlusion.

Bias secondary to similar implantation techniques remains our greatest limitation along with an absence of a venogram before device implantation.

## 5. Conclusions

Undiagnosed, asymptomatic grade 2 venous occlusions are seen in 34% patients with pacemakers at a mean follow-up of  $4.34 \pm 4.1$  years associated significantly with age >50 years, shorter time since PPI implantation to the venogram and LV dysfunction. The pathogenetic mechanisms underlying these early occlusions merit further investigations.

## Conflicts of interest

All authors have none to declare.

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