Predicting Venous Occlusion in Patients with an Implanted Electronic Cardiac Device

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Introduction

In the past 50 years, Implanted Electronic Cardiac Devices (IECD) have become an important part of therapy in the cardiac patient. It is estimated that over 400,000 devices are implanted in the United States annually. [1]

Venous stenosis, thrombosis and obstruction are common in patients with IECD and many times are an asymptomatic condition. One previous study found an incidence of 26%, with 9% of patients enrolled exhibiting complete obstruction and the rest partial obstructions.[2] Venous obstruction does not seem to be associated with age, sex, indication, insertion side, lead material or type, but may be associated with a higher number of implanted leads. [1-7]

The existence of venous stenosis and obstruction may render procedures requiring additional lead implantation more complex. Various strategies and techniques have been developed to overcome this problem including access site modification, contralateral placement, venoplasty, extraction and re-implantation and more[8]. However, all the aforementioned strategies may increase procedural risk and duration, and often require additional personnel or equipment. Therefore, early preoperative diagnosis of vein obstruction is of paramount importance.

Different screening studies for venous obstruction have been suggested.[1] The use of a venogram is considered gold standard; however, this is an invasive procedure, exposing the patient to use of contrast materials and radiation. It requires EP lab time and is usually performed at the beginning of the procedure, not allowing time for appropriate procedure planning and scheduling in case of obstruction. Additional tests include the use of duplex ultrasound, MRA, CTA and CO_2

venous imaging[9]. These tests require additional personnel and equipment to be performed and are often expensive.

Clinical experience teaches us that patients with high grade venous obstruction often have signs on physical examination, most notably collateral vessels that can be seen on the skin, over the area of venous occlusion. The validity of this finding as a predictor of venous stenosis and obstruction, however, has not been systematically studied. Additionally, we hypothesized the use of surface thermometry might be of benefit; a higher proportion of collateral circulation, closer to the skin, may result in higher surface temperature and thus predict venous stenosis and occlusion.

The ability to predict venous stenosis and obstruction by physical examination may assist the implanting physician in identifying patients who are likely to be more technically challenging during additional lead insertion. Prediction of vessel patency may prevent unnecessary use of contrast material; whereas suspicion of stenosis may help in better allocation of resources for the procedure.

Methods

The study was designed as a prospective cohort study and included patients presenting to the Electrophysiology (EP) laboratory and scheduled to undergo a procedure involving an existing trans-venous device.

The study was approved by the local ethics committee and held in accordance with GCP standards.

Patients under 18 years of age, patients unable or unwilling to provide informed consent, patients with prior history of an allergic reaction to contrast or renal insufficiency with an estimated glomerular filtration rate below 45 ml/min were excluded from the study.

After obtaining informed consent, a standardized questionnaire was filled and physical examination performed by 2 researchers, independently grading the superficial venous collateral pattern using a score ranging from 1 to 4 (1 – None seen, 2 – some seen, 3 – many seen, 4 – prominent). Figure 1. illustrates examples of patients assigned different scoring categories.

Immediately before the scheduled procedure, bilateral venography was performed. Obstruction was then assessed by another physician, blinded to collateral pattern estimation and given a score ranging from 1 to 5 (1 – none, 2 – mild obstruction (0-50%), 3- moderate obstruction (51-75%), 4 – severe obstruction (>75%) and 5 – complete obstruction.)

We speculated that surface skin temperature might correlate with collateral circulation, and measured the temperature on the implanted and non implanted side.

Statistical analysis included Spearman's Correlation to assess the reliability of the proposed collateral vessel score; a ROC curve allowed for derivation of sensitivity and specificity. Fischer's

exact test and non-parametric Mann-Whitney were used depending on variable type, to assess correlation with venous obstruction.

Disclosure and Funding

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Results

The study included 38 patients who underwent a total of 65 venograms. Patients' demographic and device data are summarized in Table 1.

Venography results showed evidence of stenosis or obstruction of the implanted side in 39.5% (n=15) of patients and complete obstruction was found in 13.2% (n=5). In the nonimplanted side there was evidence of stenosis in 15.8% of patients, (n=6) most of which (n=5) was rated mild.

Collateral circulation scores of 2 observers were averaged. On the implanted side, 42% of patients (n=16) had an average score of 1 (no collateral veins seen), 23.7% had a score of "some seen" (1.5-2.0), 10.5% had a score of "many seen" (2.5-3.0) and 13.2% had a score of "prominent" (3.5-4).

On the non-implanted side, 65.8% of patients (n=25) had a negative score (1), 21.1% (n=8) had a score of "some seen" (1.5-2) and 5.3% (n=3) had a score of "many seen" (3).

Inter-Observer correlation was calculated for the collateral score. Spearman's rho coefficient was 0.924 for the left and 0.611 for the right side ($P<0.001$) indicating strong interobserver agreement.

For practical purposes, we tested the predictive value of the collateral score to predict any degree of venous obstruction on the implanted side; to this end, a venography score of 1 (no obstruction) was regarded as 'open', while any other score was regarded as obstructed. An ROC curve was plotted (Fig. 2) with an area under the curve 0.859, ($p <0.001$), indicating excellent correlation between collateral score and any degree of venous obstruction at venography. The best cutoff value for collateral score was 1.75, yielding a sensitivity of 78.9% and specificity of 88.6% for any degree of venous obstruction.

Skin Temperature

Skin surface temperature did not show a significant and meaningful correlation with venographic findings on both the implanted and non implanted sides. (Implanted side pearson's correlation 0.336, $p=0.056$. Non – implanted side, 0.045, $p=0.82$).

Discussion

This study aimed to evaluate whether the finding of superficial veins over the upper chest on physical examination is predictive of venous obstruction in patients with an IECD.

First and foremost, our results confirm a highly significant correlation between a negative collateral score and lack of venographic evidence of obstruction.

The suggested collateral score is simple, convenient and exhibits a strong inter-observer reliability. Thus, inspection of the patient's chest during pre-procedural examination can allow one to perform risk stratification, allowing for more flexible scheduling and more efficient resource allocation.

Translating these data to practical terms, it seems reasonable to state that any significant signs of collateral venous circulation on the skin indicate that a fully patent vein is unlikely.

While contrast venography is considered gold standard, it does not always correlate with easy lead implantation. An interesting example is a patient presenting to the electrophysiology laboratory after the analysis of our data. This patient, requiring upgrade from a dual chamber pacemaker to a CRT device and thus insertion of an additional lead, had a high collateral vessel score but no obvious obstruction on venography. Despite this venographic finding, passing the additional lead proved to be impossible and the patient had to undergo extraction of the existing atrial lead to create a passageway for implantation.

Surface temperature measurement was not shown to be useful in predicting venous obstruction.

Limitations

Inclusion of patients presenting at time of device revision might create a selection bias. The relatively small sample size is reflected in a wide confidence interval of some of the test parameters.

Conclusions

In patients requiring addition of a lead to existing leads, inspection of the chest for collateral veins is a useful tool to rule out venous obstruction.

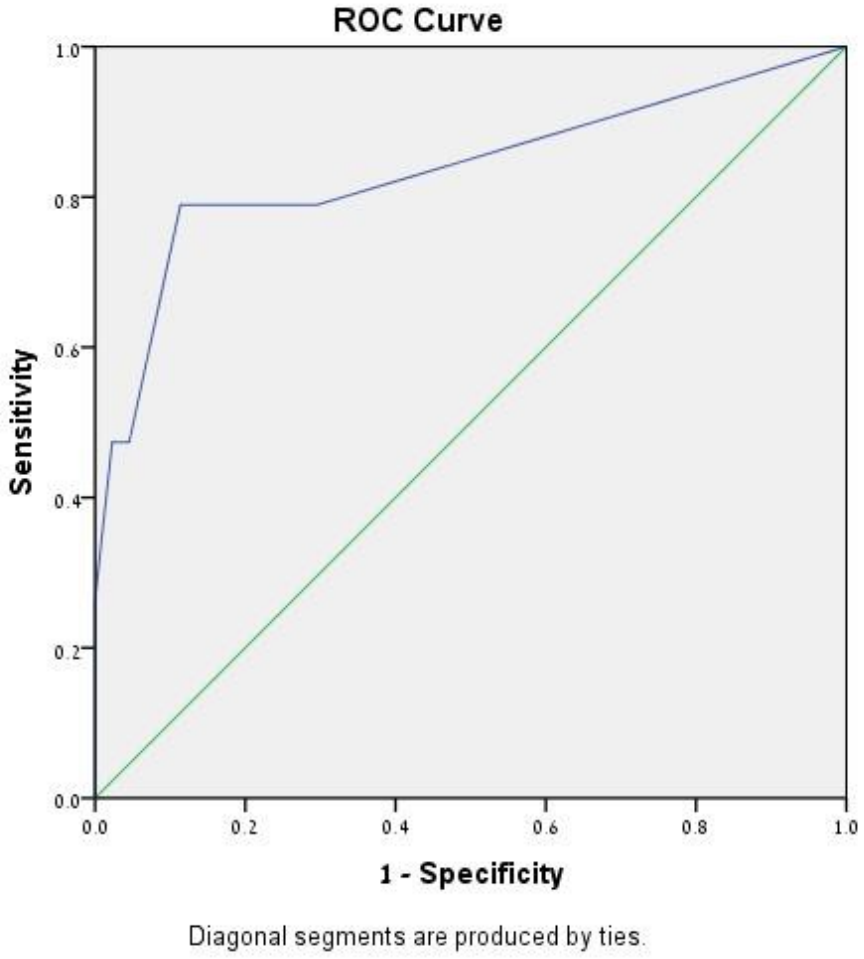
Table 1 - Patient demographics and device data

Characteristic	**Overall (n=38)**
Age	65.3 ± 17
Male	31 (81.6%)
BMI	26.5 ± 5 kg/m2
Type of device	
Pacemaker	22 (66.7%)
ICD	7 (21.2%)
CRTD	2 (6.1%)
Other	2 (6.1%)
Side of implantation	
Left	34 (89.5%)
Right	4 (10.5%)
No. of leads on implanted side:	
1	5 (13.2%)
2	27 (71.1%)
3	3 (7.9%)
4	2 (5.3%)
Time since implantation (mean)	130 ± 84 Months

Figures

Figure 1 - Example of patients in the different score categories

Figure 2 - Reciver Operator Characteristics (ROC) plot. This plot illustrates the correlation between collateral score and any degree of venous obstruction. AUC=0.859, p<0.001.



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