An 8-year single-centre experience of cardiac resynchronisation therapy: procedural success, early and late complications, and left ventricular lead performance

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Aims

Despite the increasing number of device implants worldwide, little is known about the early and late complications of cardiac resynchronisation therapy (CRT) or the incidence of these complications in patients with different heart failure aetiologies. We aim to determine procedural success and early and late complications in CRT patients.

Methods and results

All early (<90 days) and late (>90 days) complications occurring over 490 consecutive CRT procedures in 402 patients, from a large single-centre registry between 2000 and 2009 were analysed. Mean follow-up duration was 1012 ± 610 days. In addition, procedural data and long-term left ventricular (LV) lead performance were examined. The mean age of patients was 65 ± 15 years, 31% were female. The majority of devices (70%) were CRT-defibrillators. Left ventricular lead implantation was achieved after one or more than one attempt in 96.7% of patients (first procedure was successful in 95.1%). The incidence of early and late complications was 9.4% and 6.1% respectively. Infection and lead displacement were the most common complications. Dilated cardiomyopathy (DCM) was associated with significantly more complications than ischaemic cardiomyopathy ($P = 0.01$) and these occurred later in the DCM population. Long-term LV lead performance was comparable with that of right atrial and ventricular leads.

Conclusion

Transvenous implantation of the LV lead is safe and achievable for CRT with high procedural success rates. For the first time we describe the late complications from CRT in different heart failure populations. This group of patients must be kept under surveillance, not only for heart failure events but also for device-related issues. The reasons for higher complication rates in DCM patients require further evaluation.

Keywords

Cardiac resynchronisation therapy • Complications • Heart failure

Introduction

This study aims to determine procedural success and early and late complications in CRT patients. Our analysis of the data shows that left ventricular (LV) lead placement is safe and achievable with high procedural success rates, and we also describe late complications in patients with different heart failure aetiologies.

Cardiac resynchronisation therapy (CRT) has emerged as an important adjunctive treatment for selected heart failure patients.1,2 Cardiac resynchronization therapy enhances systolic function and cardiac energetics,3 reverses chamber remodelling,4 improving clinical symptoms and outcome.5–7 Left ventricular pacing may be achieved in a variety of ways, including direct access to the LV epicardial surface or using a transvenous approach via the coronary

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sinus (CS). Recently there have also been short reports describing endocardial LV pacing via a trans-septal approach.iii

As the number of CRT implants continues to increase worldwide, data on the safety of CRT implant procedures, procedural risk, and complication rates following implant are becoming increasingly important for patients and clinicians. Moreover, there are limited data describing the long-term complications of CRT, mostly derived from early experience within clinical trial settings. Published studies have focused on the benefits of CRT in different heart-failure populations. However, there are no data on the incidence and nature of complications of CRT in these patients, when analysed according to the underlying aetiology of heart failure.

To address these issues, we evaluated over 400 patients followed up for an average of 2.7 years in our centre assessing early and late outcomes of transvenous CRT system implantation, with particular focus on LV lead parameters.

**Methods**

All early and late complications from 490 consecutive CRT procedures performed on 402 patients at the Heart Hospital, University College London Hospitals NHS Trust between 2000 and 2009 were analysed. The Heart Hospital is a tertiary and national specialist centre for cardiomyopathy and adult congenital heart disease. Cardiac resynchronisation therapy implants in these populations with complex cardiac pathology were also included.

All LV lead thresholds at implant and at last follow-up were analysed. As LV pacing threshold was often measured at different pulse width setting between patients, the stimulation energy [energy \(= (2 \times \text{voltage}) \times \text{time/Resistance} \ E = V^2t/R \)] was calculated to assess changes in LV capture more accurately. Procedure times, fluoroscopy doses, and screening times were also evaluated.

Early (<90 days) and late (>90 days) complications of all CRT implants were collected and cross-referenced using procedural reports, pacing clinic records and outpatient letters on an electronic database. Inability to implant a transvenous LV lead at one or more attempts was considered a complication. In those patients in whom a complication occurred, the time in days from implant until the adverse event was recorded.

**Statistical analysis**

Continuous variables are expressed as mean ± standard deviation. Comparisons of quantitative variables were compared using two-tailed Student’s t-test for paired and unpaired data. Fisher’s exact test was used to compare proportions. A P value of <0.05 was considered statistically significant. Univariate and multivariate logistic regression analysis were used to evaluate risk factors for each complication. Variables which were significant by univariate analysis were included in the multivariate logistic regression to determine independent predictors of each complication. Time to complication in different populations was compared using Kaplan–Meier estimates.

**Implant technique and device follow-up**

Procedures were performed in one of three electrophysiology laboratories. New implants were undertaken by placement of right atrial (RA) and right ventricular (RV) leads followed by cannulation of the CS with a guiding sheath via the subclavian or cephalic route. Balloon-occlusive CS angiography was employed to guide placement of a pacing lead in the most suitable coronary vein branch. Conventional styli-guided pacing leads or over the wire approaches were used depending on the anatomy of the CS branches and the operator’s choice.

All devices were interrogated the day following initial implantation to evaluate lead parameters and device function. Subsequent device interrogation was routinely performed at 1 month, 6 months, and annually thereafter. All device and lead data were prospectively entered into a centralized device database at the time of each encounter.

**Results**

490 CRT-related procedures in 402 patients were analysed during the study period. Three hundred and thirty (82%) procedures were new device implants and 68 (18%) were device upgrades to CRT. Patient demographics are shown in Table 1. The majority of device implants were CRT-defibrillators (CRT-D) (82.6%) with CRT-pacemakers (CRT-P) comprising 17.3%. Mortality was 10.7% over a mean follow-up of 1012±610 days. No patients were lost to follow-up. Ischaemic (IHD) and idiopathic dilated cardiomyopathy (DCM) accounted for the majority of cases, with a small proportion of patients with other complex cardiomyopathies (Table 1).

Left ventricular leads from several different manufacturers were implanted with the Boston Scientific Easytrak 2© lead being the most frequently used (45.6%). Other manufacturers’ leads were only available later in the study period. The most common devices used were manufactured by Boston Scientific© (63.7%) and St Jude Medical© (28.8%) (Figure 1).

Left ventricular lead pacing threshold measurements at implant and last clinical follow-up were compared. Mean LV lead pacing threshold at implant was 1.50±0.15 mV (0.53±0.2) ms and mean pacing threshold at last follow-up was 1.40±0.17 mV (0.65±0.47) ms. Approximately half of the patients (48%) developed an increased LV lead threshold over mean follow-up duration of 1012±610 days. A similar proportion (48%) recorded a decrease. No statistically significant changes in mean stimulation energy at implant and at follow-up occurred.

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**Table 1** Patient demographics

<table>
<thead>
<tr>
<th>Aetiology subtypes (%)</th>
<th>Average age (years) 65±15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female (%)</td>
<td>79/31</td>
</tr>
<tr>
<td>NYHA class (% in each class)</td>
<td>Class I 4.6</td>
</tr>
<tr>
<td></td>
<td>Class II 22.0</td>
</tr>
<tr>
<td></td>
<td>Class III 67.0</td>
</tr>
<tr>
<td></td>
<td>Class IV 6.4</td>
</tr>
<tr>
<td>LV ejection fraction (%)</td>
<td>28.3±11.3</td>
</tr>
<tr>
<td>LV end diastolic dimension (cm)</td>
<td>6.6±0.92</td>
</tr>
<tr>
<td>Dilated cardiomyopathy</td>
<td>46.3</td>
</tr>
<tr>
<td>Ischaemic cardiomyopathy (IHD)</td>
<td>33.7</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>15.5</td>
</tr>
<tr>
<td>Adult congenital heart disease</td>
<td>2.4</td>
</tr>
<tr>
<td>Cardiomyopathy (other)</td>
<td>2.2</td>
</tr>
</tbody>
</table>

*This table shows demographic data of all patients included.*
The LV lead threshold halved in 17.7% of patients and doubled in 78 (19.7%). In only 6 of 78 patients (1.2%), pacing threshold rise was significant enough to require lead revision. In the 78 patients who had a doubling in LV lead threshold, the incidence of early complications was 6.7%. Failure to successfully implant the LV lead at the first attempt occurred in 20 patients (5%). Nine (2.3%) patients went on to have a second lead implanted in the RV outflow tract, seven (1.7%) had a successful subsequent transvenous LV implant procedure, three (0.7%) underwent surgical LV lead implantation and CRT was abandoned in one patient. This patient had been enrolled in a trial examining CRT in HCM. The research protocol dictated that if transvenous LV lead placement was not possible, the device should not be implanted. With increasing experience and improvements in lead technology and delivery kits, the incidence of failed LV lead implant decreased with time during the study period.

**Statistical analysis**

Univariate logistic regression analysis was performed to investigate the risk factors associated with complications—specifically age, gender, type of device, length of procedure, and fluoroscopy dose. Gender, length of procedure, device type (CRT-D or CRT-P) and the fluoroscopy dose did not show any significant association with the odds of developing complications. However, age and an underlying aetiology of heart failure were predictors. Compared with IHD, DCM patients had a significantly higher risk of complications. The odds of developing a complication in DCM was 2.4 (95% CI: 1.28; 4.48, P = 0.005) times higher than in those with IHD. The association between the development of any complication in patients with other complex cardiomyopathy (hypertrophic cardiomyopathy, adult congenital heart disease, arrhythmogenic RV dysplasia, Fabry’s disease and LV non-compaction) was not significantly different from that seen with IHD. Although both HCM and other complex heart disease patients had a trend towards increasing complications, with odds ratios of 1.88 (95% CI: 0.84; 4.20, P = 0.124) and 2.33 (95% CI: 0.81; 6.64, P = 0.115), respectively. Increasing age was associated with reducing odds of developing any complication [odds ratio was 0.98 (95% CI: 0.97–0.99, P = 0.017)].

All risk factors were incorporated into a model for multivariate analysis to obtain adjusted measures of association. Independent of gender, age, type of device inserted, length of procedure and the fluoroscopy dose, patients with DCM still had significantly more complications compared with patients with IHD, with an odds ratio of 2.76 (95% CI: 1.04; 7.31, P = 0.04).

Underlying aetiology was also investigated as time to event analysis. This showed a significant increase in the hazard of developing complications over time in patients with DCM as compared with those with IHD [hazard ratio 1.96 (95% CI: 1.01; 3.79, P = 0.04)]. The mean time to development of a complication in the DCM group was 40.8 months as compared with 13.6 months in the ischaemic group.

In the logistic regression analysis, the complex cardiomyopathy group did not have a significant increase in their odds of developing complications compared with the IHD group. However, when analysed over time, this group showed more early complication events and outcome curves were significantly different [hazard ratio 3.09 (95% CI: 1.16; 8.25, P = 0.024)].

**Procedural success**

After one or more than one attempts, transvenous LV lead placement was successful in 96.7% of patients. Failure to successfully implant the LV lead at the first attempt occurred in 20 patients (5%). Nine (2.3%) patients went on to have a second lead implanted in the RV outflow tract, seven (1.7%) had a successful subsequent transvenous LV implant procedure, three (0.7%) underwent surgical LV lead implantation and CRT was abandoned in one patient. This patient had been enrolled in a trial examining CRT in HCM. The research protocol dictated that if transvenous LV lead placement was not possible, the device should not be implanted. With increasing experience and improvements in lead technology and delivery kits, the incidence of failed LV lead implant decreased with time during the study period.
Unsuccessful LV lead placement was not influenced by aetiology of heart failure, but 55% of these patients were found to be in atrial fibrillation. Reasons for unsuccessful lead placement included:

1. Tortuous coronary sinus or target branches (seven patients)
2. Valve encountered at the coronary sinus (three patients)
3. Poor lead stability (three patients)
4. Coronary sinus dissection (three patients)
5. Inability to cannulate the coronary sinus (two patients)
6. Phrenic nerve stimulation (one patient).

In one patient the reason for failure remained unclear.

**Procedure time**

Mean procedure time for new implants was 167.0 ± 109 min. Mean fluoroscopy time was 30.5 ± 9.3 min. In cases with early or late complications, mean procedure duration was longer at 201.5 ± 103.1 min and mean fluoroscopy time also increased to 69.0 ± 18 min reflecting the complexity of the case. While it may be expected that procedure and fluoroscopy times would decrease as operator experience and lead delivery tools improved, we found no significant reduction in these over the course of the study period. This may partly be due to the inclusion of patients with adult congenital heart disease and other complex cardiomyopathies, in the later stages of the study period.

**Discussion**

A large number of clinical studies have elucidated the benefits of CRT, but there are very limited data describing late complications and long-term performance of CRT devices. This study is the largest reported single-centre patient cohort with one of the longest follow-up registries for CRT devices. We found an acceptably low overall incidence of early complications (9.4% which includes failure to implant an LV lead) in keeping with previous findings. However, our results demonstrate that this group of patients need long-term surveillance for heart failure events and late device-related complications which have a significant incidence (6.1%).

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Table 2 Early and late complications by aetiology

<table>
<thead>
<tr>
<th>Aetiology (%)</th>
<th>Percentage of early complications (&lt;90 days) (%)</th>
<th>Percentage of late complications (&gt;90 days) (%)</th>
<th>Mean time to late complication (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemic cardiomyopathy (34)</td>
<td>8.1</td>
<td>3.7</td>
<td>13.6</td>
</tr>
<tr>
<td>Dilated cardiomyopathy (46)</td>
<td>9.4</td>
<td>11.6</td>
<td>40.8</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy (16)</td>
<td>12.6</td>
<td>7.9</td>
<td>16.3</td>
</tr>
<tr>
<td>Other cardiomyopathy (2)</td>
<td>25</td>
<td>87</td>
<td>13.6</td>
</tr>
<tr>
<td>Adult congenital heart disease (2)</td>
<td>12.7</td>
<td>25</td>
<td>20.6</td>
</tr>
</tbody>
</table>

*A This table shows the number of early and late complications classified by aetiology.

Table 3 Early and late complications by complication type

<table>
<thead>
<tr>
<th>Complication type</th>
<th>Early (&lt;90 days) (n)</th>
<th>Late (&gt;90 days) (n)</th>
<th>Mean time to late complication (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>2</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Phrenic nerve stimulation requiring revision</td>
<td>3</td>
<td>4</td>
<td>11.4 (±8)</td>
</tr>
<tr>
<td>Infection</td>
<td>7</td>
<td>7</td>
<td>14.9 (±11)</td>
</tr>
<tr>
<td>Noise on RV/RA lead</td>
<td>1</td>
<td>3</td>
<td>17.0 (±22)</td>
</tr>
<tr>
<td>Box migration</td>
<td>2</td>
<td>1</td>
<td>15.0</td>
</tr>
<tr>
<td>RV/RA/LV lead fracture</td>
<td>1</td>
<td>4</td>
<td>33.1</td>
</tr>
<tr>
<td>Lead erosion</td>
<td>3</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>RV/RA lead displacement</td>
<td>6</td>
<td>6</td>
<td>4.9 (±2)</td>
</tr>
<tr>
<td>Inability to implant LV lead</td>
<td>13</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>LV lead displacement</td>
<td>5</td>
<td>5</td>
<td>6.8 (±4)</td>
</tr>
<tr>
<td>Total</td>
<td>44 (9.4%)</td>
<td>30 (6.1%)</td>
<td>–</td>
</tr>
</tbody>
</table>

*A This table shows all early and late complications and the mean time to their occurrence.
With growing experience, successful LV lead implantation can be achieved and in this series 96.7% were successful. Infection and lead displacement remain the most common complications of CRT implantation. The overall incidence of LV lead displacement over a follow-up of 2.7 ± 1.8 years is only 2.4% and not greater than that of RA or RV leads (2.5%). In addition, our registry confirms that LV leads have a good long-term performance with little change in electrical parameters.

**Early complications**

The incidence of peri-procedural complications occurring within 90 days of the implant was 9.4% and is considerably lower than previously described. Data regarding the incidence of complications secondary to CRT implants are largely derived from clinical trials of CRT. Leon et al. evaluated the success and complication rates in 2000 patients from three large clinical studies of CRT (the MIRACLE study program): the Multicenter InSync Randomized Clinical Evaluation (MIRACLE) study, the MIRACLE Implantable Cardioverter-Defibrillator (MIRACLE ICD) study, and the InSync III study. The overall perioperative (day 0 to day 7) and postoperative (day 7–6 months following device implant) complications were 13.8% and 10%, respectively, with a 30-day mortality of 1.5%.

In the large multi-centre experience in the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION) trial, moderate or severe peri-procedural events occurred in 18% of CRT patients. Similar to our findings, there was no difference in the incidence of significant device-related adverse events (coronary venous perforation and coronary venous tamponade) at the time of the procedure, based on device-type \(P = 0.42\). Most recently, in the MADIT-CRT trial, patients were randomized to receive either CRT-D (1089 patients) or ICD alone (781 patients) (Table 4).

**Late complications**

There is little published literature detailing late complications of CRT. While the percentage of late complications (6.1%) remains lower than those which occur early (9.4%), centres responsible for care of CRT patients must remain vigilant since late device-related complications do occur in a significant proportion. We have reported in detail for the first time the incidence and nature of long-term complications in this patient population. During a mean follow-up of 2.7 ± 1.8 years, infection and late lead displacement remain the most common. The incidence of these does not tail off as may be expected but remains very similar to that observed in the initial post-operative period.

In MADIT-CRT, the overall incidence of procedure or device-related complications in the CRT-D group was 28.5%, although most of these occurred within the first 3 months. From our experience, complications continue to occur in CRT patients after the first 3 months after implant, and these patients must remain under close surveillance.

Previous reports have suggested that the benefits of CRT may be less marked in IHD patients. There is no published evaluation examining whether these two populations have differences in CRT complication rates. Our data show for the first time that patients with DCM have a significantly higher overall incidence of complications compared to those in the ischaemic group and that these are more delayed in the DCM population.

The reasons why such a difference should exist are unclear, as there were no significant differences in LV dimensions, ejection fraction, or the number of potential target branches for lead implantation. However, whereas scar tissue of ischaemic origin tends to be endocardial and/or transmural, the scar in the DCM population by in large tends to be epicardial. There may also be a difference in evolution of scar and remodelling between these two groups with time. These factors will influence the stability of LV pacing leading to increased late complications in the DCM population. In addition, the DCM population were on average 10 years (95% CI: 7.6; 12.9, \(P < 0.001\)) younger than those with IHD. The DCM group is composed of a more heterogeneous population with a lower average age and patients may have more active lifestyles leading to a higher incidence of lead wear and fractures that could contribute to late complications.

Finally, progression of coronary artery disease and subsequent ischaemic events are a cause of further clinical deterioration in ischaemic patients. Thus, the observation of a higher late complication rate in patients with DCM may simply be due to earlier attrition of patients in the IHD group who therefore are not alive to suffer complications. However, in the recent analysis of the Care HF study, the long-term effects of CRT on symptoms, quality of life, morbidity, and mortality were similar in patients with and without ischaemic heart disease.

With univariate analysis increasing age was associated with fewer complications. This was contrary to the conventional knowledge of older age being associated with increased risk of complications. However, the inclusion of heart failure aetiology into the univariate model with age rendered the association between age and the development of complications non-significant. The younger average age in the DCM group, which had a higher complication rate, resulted in the erroneous negative association of increasing age with a reduction in the incidence of complications.

Our registry also included a small proportion of patients who did not have conventional indications for CRT, such as patients with adult congenital heart disease and more complex forms of LV lead reposition.

**Table 4 Early complications of cardiac resynchronisation therapy implant compared to MADIT-CRT data**

<table>
<thead>
<tr>
<th>Complication</th>
<th>MADIT–CRT (CRT-D group) 30 days</th>
<th>Heart hospital CRT-P/CRT-D 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumothorax</td>
<td>1.5%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Infection</td>
<td>1.1%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Haematoma requiring evacuation</td>
<td>3.3%</td>
<td>0%</td>
</tr>
<tr>
<td>Coronary venous dissection with effusion</td>
<td>0.5%</td>
<td>0%</td>
</tr>
<tr>
<td>LV lead reposition</td>
<td>4%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

*This table compares our complication rates with the data from the MADIT-CRT study.*
cardiomyopathy often with pacing indications. While the numbers of these patients were small, there was a trend towards increased complications in this group which may be attributed to more challenging complex anatomy and longer procedure times.

**Successful left ventricular lead implantation and long-term left ventricular lead stability**

Successful LV lead implantation was achieved in 95% of patients after the first procedure and after further procedures we achieved an overall LV lead implant success rate of 96.7%. This figure is higher than that seen in the COMPANION,6 MIRACLE,7 Cardiac Resynchronisation–Heart Failure,8,9 MUSTIC10 and CONTAK-CD11 studies (91%, 92%, 95%, 92% and 91%, respectively).

One limitation of our study is the lack of data regarding operator experience as a determinant of procedural success or incidence of complications. However, all procedures were performed by, or under the supervision of, an experienced specialist. Achieving a high implant success of just under 97% is probably multifactorial. We have a group approach to CRT and following a procedure which has been unsuccessful there is a routine review of the implant details. Coronary sinus anatomy, technical aspects, and difficulties encountered during the procedure are assessed, before a group consensus is reached as to whether a further attempt at implant is likely to be successful and if so, the strategy which is most likely to achieve this. Advances in the subtypes of guide catheters available, lead technology, and advances in pre-procedural imaging have all contributed to our high success rate for CRT implants.

We describe one of the longest CRT registries with a mean follow-up of 3 years. Left ventricular lead electrical measurements remain stable after implantation, with no significant differences in threshold over time. Our data differ from that of some studies where the LV stimulation threshold increased with time. However, in keeping with our findings and others, Lin et al.21 described that LV lead thresholds remain stable at long-term follow-up.

We found the overall incidence of LV lead displacement requiring revision was 2.5%, considerably lower than the rates of between 8% and 30% previously described. RA and RV lead displacement was not significantly different from lead placement via the coronary sinus provides a safe and feasible option.

Conclusions

Our experience from one of the largest single centre registries of patients with long-term follow-up confirms that transvenous LV lead placement via the coronary sinus provides a safe and feasible method to achieve CRT. Our findings show that the LV lead remains stable over the long term, comparable to RA and RV leads. While long-term complications of CRT are low, they are prevalent enough to warrant close clinical monitoring of patients. Our study suggests that patients with idiopathic DCM have a higher incidence of late complications, though the reasons for these differences require further investigation.

Conflict of interest: none declared.

**References**

A 62-year-old man with a history of ventricular tachycardia and coronary artery bypass graft surgery underwent implantable cardioverter-defibrillator lead extraction with an excimer laser sheath because of a lead failure and inappropriate shocks. The procedure was complicated with an iatrogenic arteriovenous fistula between the left internal mammary artery (LIMA) and innominate vein occurred, resulting in massive bleeding into the mediastinum (Figure 1A). Since the LIMA had been employed as a coronary artery bypass graft, embolization of this vessel was not an option. A 3.0 × 19 mm covered stent (Jostent, Abbott Vascular, Abbott Park, IL, USA) was then deployed at the site of fistula (Figure 1B). As a result, the fistula was closed and perfusion of the coronary arteries was maintained (Figure 1C).

An iatrogenic arteriovenous fistula between the LIMA and innominate vein can occur as a complication of lead extraction. This case demonstrates that while the likelihood of damage to the LIMA during lead extraction may be small, its consequences may be complex and require novel solutions. The use of a covered coronary artery stent in the LIMA graft effectively controlled bleeding, closed the fistula between the graft and the innominate vein, and protected patency of the graft.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/Innominate-vein-to-left-internal-mammary-artery.pdf