Complex cardiac pacing in the setting of a district general hospital: procedural success and complications

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ABSTRACT

Background and purpose Complex cardiac pacing with either an implantable cardiovertor defibrillator (ICD) or a biventricular pacemaker with pacing only (CRT-P) or biventricular pacemaker with implantable cardiovertor defibrillator (CRT-D) plays an important role in the management of patients with heart failure. However, device implantation is associated with rare but significant complications which may limit the number of centres offering this treatment. The aim of this study is to define procedural success and complication rates associated with implantation of complex implantable cardiac devices in a district general hospital.

Methods and subjects The pacing records of all the patients who underwent complex cardiac pacing (ICD, CRT-P and CRT-D) between January 2010 and December 2011 were reviewed. Information on clinical characteristics, pacing indications, venous access, implantation data, lead stability at follow-up, and procedure-related complications were obtained.

Results A total of 151 devices (60 CRT-Ds, 55 CRT-Ps and 36 ICDs), were implanted between January 2010 and December 2011 with a median follow-up of 12 months. Overall transvenous procedural success rate was 99.3%. 14 (9.3%) out of the 151 patients suffered a complication. There were no procedure-related deaths, and lead displacement (5.3%) was the most common complication. Other complications included pocket haematoma and phrenic nerve stimulation (1.3% and 3.4%, respectively). There were no cases of pneumothorax, cardiac tamponade, device-related infection, symptomatic venous thrombosis and stroke. Lead thresholds, in particular that of the left ventricular lead, remained stable during the follow-up period indicating persistent delivery of cardiac resynchronisation therapy in the group receiving CRT systems.

Conclusions In the presence of necessary clinical expertise, complex cardiac devices can be implanted successfully and with a high degree of safety in the setting of a district general hospital.

INTRODUCTION

Heart failure continues to subtend a significant burden of disease globally.[1] Its prevalence and incidence rates have reached epidemic proportions in the developed countries.[1][2] In North America and Europe, prevalence is estimated to be approximately 2% with an incidence approaching 5–10 per 1000 person per year.[3] Heart failure substantially affects longevity and quality of life of the afflicted individuals, and consumes a significant proportion of healthcare resources.[4] Nevertheless, advances in medical therapy and use of cardiac implantable electronic devices (CIED) has led to a reduction in morbidity and mortality associated with heart failure.[5–10] Implantation rates of implantable cardioverter defibrillators (ICD), cardiac resynchronisation therapy with pacing only (CRT-P), and cardiac resynchronisation therapy with defibrillation capability (CRT-D) have risen across Europe in the recent years.[11] However, there is a large variation in implantation rates between European countries with significantly low uptake in the UK when compared to Germany and Italy[12] (figure 1). Further, there is a suggestion that a big gap exists between the numbers of patients who meet the criteria for ICD and/or CRT implantation and the numbers that actually receive such a device.[11][12] This discrepancy between 'supply and demand' is expected to be further exacerbated by emerging evidence that benefits of CRT are not limited to severe heart failure but can be extrapolated to mild to moderate heart failure.[13][14] One strategy of narrowing this gap would be to broaden the 'provider base' and taking the implantation service closer to the patient.

Implantation of complex cardiac devices (ICDs, CRT-P and CRT-D) requires a high level of procedural and technical experience, and is associated with rare but significant complications which may limit the number of centres offering this type of therapy. In the UK, majority of complex cardiac devices are implanted in tertiary referral centres with district general hospitals performing a small number of procedures. In this study, we report our experience of device implantation over a 2-year period in the setting of a district general hospital, and aim to show that the procedural success rate and safety is comparable to that reported in large randomised trials. Notwithstanding, data from these trials may not be fully applicable to everyday practice because of selection bias in operators and patients. Further, new implantation techniques like axillary vein puncture for venous access and multi-site pacing have been introduced, and many patients are taking dual antiplatelet therapy or anticoagulant agents. Therefore, procedural complications may have changed or become more variable.
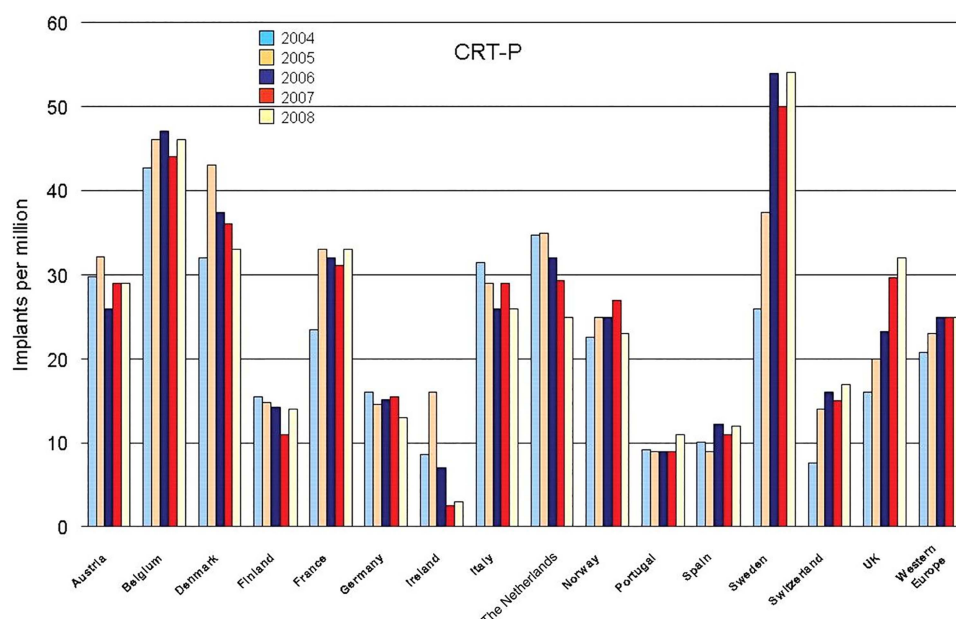
METHODS

Study population

Study patients were identified from the cardiac centre's procedural log and cross-checked with the local cardiac device registry. Clinical and technical data for all patients undergoing device implantation is collected prospectively and recorded in a 'device

Figure 1 Cardiac resynchronisation therapy (CRT) implantation across a number of European countries. Reproduced with permission from Oxford University Press.

folder'. The latter is continuously updated at every elective or emergency visit to the device clinic or hospital. For the purpose of our study, the data thus captured has been retrospectively analysed. A total of 151 CIED (60 CRT-Ds, 55 CRT-Ps, and 36 ICDs) implantations took place over a period of 2 years (January 2010–December 2011). Of these, 137 were new system implants and the rest were upgrades.

Device implantation

Indications for device implantation were based on guidelines.[15–17] Antibiotic prophylaxis was given in all patients with 1.5 g of cefuroxime (or 400 mgs of Tiecoplanin if allergic to penicillin) intravenously just prior to the procedure. Postimplant oral antibiotics were prescribed for 3 days (coamoxiclav or clarithromycin in cases of penicillin allergy). If the patient were on an anticoagulant, this was temporarily discontinued to achieve an International normalised ration (INR) value of less than 1.7. If bridging heparin was indicated, then low molecular weight heparin (LMWH) was used and the last dose of the LMWH injection was given no less than 24 h prior to the procedure. Postimplant, LMWH was restarted after 12–24 h. Warfarin was reintroduced after 2 days. Antiplatelet therapy with aspirin and/or clopidogrel was allowed to continue. Venous access for leads was achieved either via cephalic vein cut down and/or subclavian vein puncture (including axillary vein puncture using the extra-thoracic approach). Active fixation leads were used in the right atrium and right ventricle, whereas most commonly used leads to pace the left ventricle were passive fixation. Atrial leads were implanted at various positions in the right atrium depending upon where good pacing and sensing parameters were achieved. Right ventricular leads (pacing and ICD leads) were predominantly targeted to the basal septal position. If the lead position was felt to be unstable, or pacing and/or sensing parameters were suboptimal, it was then moved to the apical position. Left ventricular (LV) leads were usually targeted to the posterolateral veins. Left and right anterior oblique fluoroscopy views were routinely used to guide lead positioning.

Two cardiologists (MF and MJ) with subspeciality training in complex cardiac device implantation undertook all the procedures, with majority of the implants being performed by cardiologist MF.

Follow-up

Clinical and technical evaluation of the patient and implanted device were undertaken the following day after the procedure. This included assessment of the pocket, ECG, chest X-ray, echocardiography to exclude pericardial effusion, device interrogation and programming. Further appropriate tests were carried out if a complication was identified or suspected. Follow-up visits were at 4 weeks, 3 months and then every 6 months. In case of a CRT, echo-optimisation of the device was performed at the first clinic visit at 4 weeks.

Complications

A complication was defined as any adverse event requiring reoperation or other form of intervention with the subsequent need to prolong hospital stay. Pocket haematoma or haemorrhage was defined as swelling of the pocket and/or a fall in blood haemoglobin levels by 2 g or more and requiring reoperation. Symptomatic deep vein thrombosis was defined as a combination of appropriate symptoms and signs with confirmation of venous occlusion by contrast venography or ultrasonography. Device system infection was defined as pocket infection or fever with positive blood cultures with no other focus of infection. Lead displacement was diagnosed as suboptimal sensing and/or pacing parameters with or without radiological evidence (macrodisplacement or microdisplacement) of lead dislodgement. Pneumothorax was qualified as absence of lung markings over the ipsilateral lung field and treated with aspiration or chest drain. Cardiac tamponade was diagnosed as pericardial effusion causing haemodynamic compromise and requiring pericardiocentesis. Stroke was defined as transient or permanent loss of focal or global cerebral function due to a vascular cause.

RESULTS
Clinical characteristics

One hundred and fifteen patients had CRT implantation with a median age of 76 years (IQR 67.5–80.5), and 92 (80%) of

Table 1 Clinical characteristics of patients in ICD and CRT groups

Patient characterstics	CRT	ICD
Demographics		
Age (median)	76 (67.5–80.5)	72 (67–81)
Male (%)	80	91
Heart failure aetiology (%)		
Ischaemic	52	66
Non-ischaemic	48	34
Past history (%)		
Diabetes mellitus	20	15
Chronic lung disease	16	23
CABG	18	30
PCI	10	46
History of ablation	0	0
Prior device (PPM/ICD)	10	0
VF/sustained VT	16	18
ECG (%)		
Mean heart rate	72 (±15)	73 (±12)
Sinus rhythm	75	77
Atrial fibrillation	25	23
QRS complex (%)		
LBBB	65	12
RBBB	10	4
Other	25	84
QRS duration <120	7	27
QRS duration 120–149	13	65
QRS duration >149	80	8
NYHA class		
NYHA class I	1	1
NYHA class II	28	44
NYHA class III	69	55
NHYA class IV	2	0
Echocardiogrphy		
Mean ejection fraction %		
<25%	41	40
25–35%	43	16
>35%	16	44
LV end-diastolic diameter (mm)	62	60
LV end-systolic diameter (mm)	54	50
Mitral regurgitation %		
No MR	21	29
Mild MR	50	47
Moderate MR	27	21
Severe MR	2	3
Sedation/anaesthesia (%)		
Local	98	100
General anaesthetic	2	0
RV lead position (%)		
Basal septal	59	19
Apical	41	81
LV lead position (%)		NA
Anterior	3	
Anterolateral	8	
Lateral	35	
Posterolateral	54	
Middle cardiac vein	0	
Periprocedure complications		
Bleeding	0	0
Pocket haematoma	1.7	0
Pneumothorax	0	0
Pericardial tamponade	0	0
		Continued

Table 1 Continued

Patient characteristics	CRT	ICD
Lead displacement	2.5	5.6
Phrenic nerve stimulation	3.5	0
Medical treatment at discharge		
Diuretic	75	57
ACEI	82	93
β blocker	78	82
Aldosterone receptor blocker	36	50

ACEI, angiotensin converting enzyme inhibitor; CRT, cardiac resynchronisation therapy; ICD, implantable cardiovertor defibrillator; LV, left ventricular; LBBB, left bundle branch block; NYHA, New York Heart Association; RV, right ventriclular.

these belonged to the male gender. Fifty-two per cent had ischaemic aetiology, and 69% were in New York Heart Association (NYHA) class III. Twelve-lead resting ECGs revealed that 25% were in atrial fibrillation and left bundle branch block (LBBB) was present in 69%. Eighty per cent had a QRS duration ≥149 ms. Median ejection fraction was 27% (IQR 20–35) with a mean LV end diastolic diameter of 62 mm. Twenty-nine per cent of the patients had at least moderate mitral regurgitation prior to device implantation. The ICD group consisted of 36 patients with a median age of 72 years (IQR 67–81) of which 34 (95.5%) were male. Ischaemia was the underlying aetiology in 66%, and 23% were in atrial fibrillation (AF). Median ejection fraction of this group was 26% (IQR 20–39) with a mean LV end diastolic diameter of 61 mm (table 1).

CLINICAL CHARACTERISTICS
Implantation data
One hundred and one patients (88%) had a new CRT system implant and the remaining were system upgrades. Multisite pacing was employed in eight (7%) cases. We were unable to implant a LV lead in one (0.8%) patient who was therefore excluded from the analysis. One patient required a second attempt at LV lead placement. All ICDs were new system implants. Except for two cases (1.3%) where patients requested a general anaesthetic, all remaining implants were performed under local anaesthesia and conscious sedation. All patients had received prophylactic antibiotics. In the CRT group, 70 right ventriclular (RV) leads (59%) were positioned in the basal septum and the remaining in the right ventricular apex (RVA). Sixty-four LV leads (54%) were placed in a posterolateral, and 42 (35%) in a lateral position. Within the ICD cohort, 29 ICD leads (80.5%) were positioned in the RVA.

Follow-up and stimulation thresholds
Median follow-up of the entire cohort was 12 months. Mean stimulation thresholds at implantation were RA-lead 0.85 ±0.45 V, RV-lead 0.47±0.15 V, and LV-lead 1.7±1.25 V. At the last follow-up visit, the thresholds were recorded as RA-lead 0.5 ±0.39 V, RV-lead 0.68±0.24 V, and LV-lead 1.14±0.69 V. These results indicate that the thresholds remained stable during follow-up thereby confirming a consistent delivery of CRT in the cohort that had undergone CRT implantation (table 2 and figure 2).

LEAD THRESHOLD
Complications
There were no procedure-related deaths. Fourteen patients (9.3%) suffered a complication most of which occurred during

Table 2 Mean thresholds at implantation and last follow-up visits

	Threshold at implant	Threshold at last follow-up
RA	0.85	0.5
RV	0.47	0.68
LV	1.7	1.14

LV, left ventricular; RV, right ventriclular.

the procedure or within 24 h thereafter. The most common complication was lead dislodgement with two cases in the ICD group (1 atrial and 1 RV lead) and six in the CRT cohort (4 LV and 2 RV leads). Four patients had phrenic nerve stimulation which could not be eliminated by reprogramming, and required lead revisions. Two patients developed pocket haematoma necessitating evacuation. No cases of pneumothorax, cardiac tamponade, cardiac perforation, system infection, vein thrombosis or stroke were evident during the follow-up period.

DISCUSSION
Procedural success
The main observation from our analysis of complex cardiac device implantation in a district general hospital was a 99.3% overall transvenous procedural success rate (99.2% for the CRT group). This high degree of successful CRT implantation is approximately 10% better than observed in previous historical controlled studies, where it ranged between 89% and 91%.[18–20] CARE-HF[9] reported a procedural success of 95.6%, and this was partly attributable to the study protocol which allowed up to three transvenous implant attempts. More recently MADIT-CRT (Multi-centre Automatic Defibrillator Implantation Trial)[13] and RAFT (Resynchronisation–Defibrillation for Ambulatory Heart Failure Trial)[14] described success rates of 92.5% and 94.7%, respectively. Our superior result is probably attributable to the evolution in device technology, and the high level of local procedural expertise and skill (cardiologist MF who undertook most of the implants had received training in coronary intervention and device implantation which puts him in a unique position to use and transfer skills acquired in one subspeciality to another). Effective cardiac resynchronisation therapy depends on accurate implantation of the atriobiventricular (or atriotriventricular) system which involves several technical challenges.[21] Improper lead placement could lead to therapeutic failure, and hence, proper positioning

of all leads is important. Cannulation of the coronary sinus, occlusive retrograde venography and placement of the LV lead into a target vessel are therefore critical steps in a successful implant. Difficulties may be encountered due to changes in anatomical landmarks secondary to significant cardiac remodelling, prominent Eustachian or Thebesian valves, previous cardiac surgery, and highly variable anatomy of the coronary venous system. However, the CARE-HF investigators[21] showed that neither the underlying heart disease nor the presence of severe functional disability predicted procedural success. The only variable related to successful CRT implant was operator experience. This observation is concordant with previous reports of a positive effect conferred by operator experience in implantation outcomes of single-chamber and dual-chamber pacemakers.
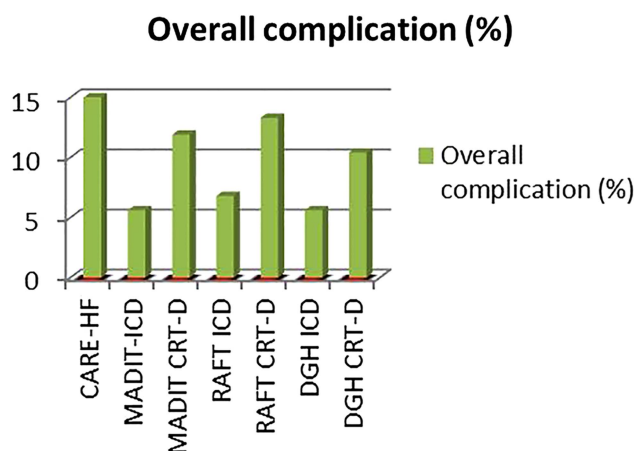
Complications
Implantation of CRT devices is technically complex and at times challenging. Given the relative fragility of patients with advanced heart failure, safety issues, therefore, deserve special attention.[21] Further assessment of current complication rates may be relevant due to addition of new variables, such as dual antiplatelet therapy, which can potentially increase complications or improvements in device technology and implantation techniques that could decrease them. Complication rates can be derived from randomised trials, retrospective surveys, and registries. Controlled studies of conventional pacing have shown that rates of complications are directly related to device complexity, in particular, the number of leads that are implanted.[22][23] For example, in CTOPP[22] and UK-PACE (United Kingdom Pacing and Cardiovascular Events trial),[23] complications were almost double in recipients of dual as opposed to single-chamber pacemakers. This increased risk associated with dual-chamber pacing was attributed to lead-related complications, particularly atrial lead dislodgement. A registry-based prospective multicentre pacing study[24] reported in-hospital complication rates of 10.1%. In CARE-HF, complication rates in excess of 15% were observed in the CRT group and, more recently, slightly lower rates were reported in MADIT-CRT (11.9% in CRT-D and 5.6% in ICD groups) and RAFT (13.3% in CRT-D and 6.8% in ICD cohorts). We observed adverse event rates of 9.3% in our study population (10.4% in CRT recipients and 5.6% in the ICD group) which are relatively modest and comparable to the results alluded to earlier (see figures 3 and 4).

These adverse events, in particular those seen in the CRT recipients are a composite of common complications associated
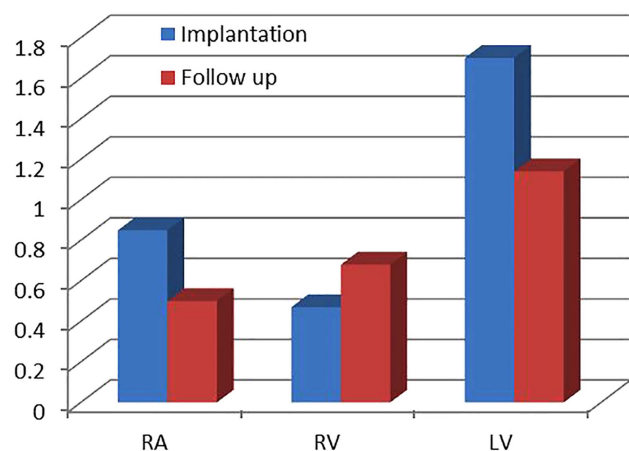
Figure 2 Lead threshold.
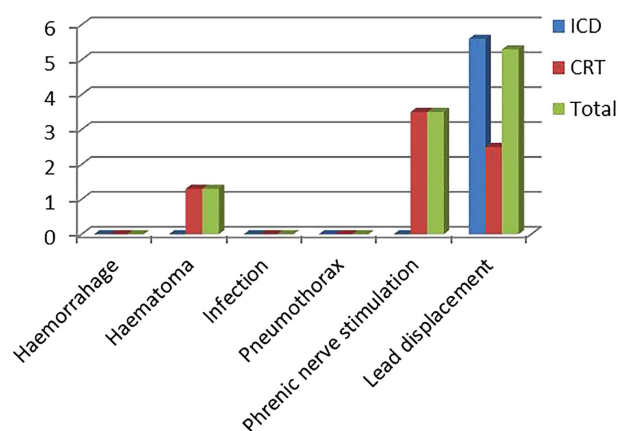
Figure 3 Procedure-related complications.

Overall complication (%)

Figure 4 The rate of procedure-related complications across a number of trials compared to the complication rate in our study.

with any pacemaker implantation, the additional risk incurred with the implantation of an atrial lead, and the specific risks associated with implanting an LV lead. Although, these specific LV lead-related complications resulted in reintervention in approximately 7% of cases, we believe this risk is acceptable given the clinical benefit conferred by cardiac resynchronisation therapy.[9]

Lead displacement (5.3%) was the most common complication in our study, and its incidence is comparable to previous reports.[13 14 21 24] Interestingly, none of the RV leads positioned into the septum dislodged, suggesting that a strategy of deploying an active fixation RV lead (either pacing or ICD lead) in a septal position does not necessarily result in an increase in lead displacement rates. This may be particularly relevant in recipients of CRT, as septal positioning of the RV lead may maximise the anatomic distance between the LV and RV leads, a factor that has been advocated to enhance the likelihood of response to CRT.[25]

Pocket haematoma requiring evacuation developed in two cases (1.3%), and its incidence is similar to published data.[13 14 21] Both these patients were on dual antiplatelet therapy at the time of device implantation. Antiplatelet and anticoagulation therapy is common in contemporary cardiac device implantation population. And high-dose heparin

treatment, or dual antiplatelet therapy, is known to predict these complications.[26] Perhaps avoiding combinations of these drugs (if clinically safe to do so) and the local use of flowable haemostat consisting of collagen/thrombin suspension in high-risk patients might reduce the incidence of this complication.[27]

We had four cases (3.4%) of phrenic nerve stimulation, all of which required repositioning of the LV lead as diaphragmatic capture could not be eliminated despite changing the pacing vectors. The incidence of this complication was again not higher than previous reports.[13 14 21] With evolution of lead technology it is hoped that this complication could be minimised or completely eliminated. There is now data to suggest that the use of quadripolar LV leads may help in achieving this goal.[28]

There were no cases of pneumothorax or cardiac tamponade in our study population. Similarly, no device system infection was identified. The latter may be partly due to the relatively short follow-up (median of 12 months). No patient developed symptomatic deep vein thrombosis of the ipsilateral upper extremity, and we did not seek asymptomatic vein thrombosis which perhaps occurs more frequently.[29]

Study population
Our study population was significantly older than the patients reported in some of the contemporary device trials (see table 3).[16 20 21] This clearly reflects selection bias in controlled studies, but a similar pattern was noted when we compared our cohort to the recently published European CRT survey.[30]

This may partly be due to a similar selection bias in implantation practice within the centres contributing to the survey. Mean ejection fraction, percentage of patients in NYHA class III, and incidence of AF are similar to that noted in the survey, but the uptake of β-blockers and inhibitors of the renin-angiotensin-aldosterone axis was lower, suggesting a relatively higher rate of intolerance of these medications in a predominantly older population with moderate to severe heart failure.

Further, 7% of the CRT recipients had QRS duration of less than 120 ms and 16% had an ejection fraction greater than 35%. These percentages are not very different from those described in the European CRT survey (9% and 17%, respectively). This small group of patients, who had received CRT systems in apparent deviation to the guidelines, primarily had a Brady indication for pacing. Given their symptoms of heart

Table 3 Patient characteristics across different trials and in our study

	CARE-HF	MADIT ICD	MADIT CRT-D	RAFT ICD	RAFT CRT-D	CRT survey	DGH ICD	DGH CRT
Number of patients	409	731	1089	904	894	2438	36	115
Mean age (years)	65	64	65	66.2	66.1	68	72	76
Male (%)	73	75.6	74.7	81	84.8	76	91	80
Ischaemic heart disease	38	54.9	55	64.9	68.7	51	66	52
NYHA class III (%)	64	10	10	19.2	20.8	70	55	69
LV ejection fraction (%)	26	24	24	22.6	22.6	26	49	28
LV diastolic diameter (mm)	72	N/A	N/A	N/A	N/A	66	62	62
Atrial fibrillation (%)	0	12.6	11.1	12.7	12.8	23	23	25
Heart rate (%)	70	N/A	N/A	N/A	N/A	70	73	72
Diuretics (%)	99	72.9	75.7	83.6	84.7	88	57	75
ARB/ACEI (%)	85	97.7	97.8	97.1	96.1	91	93	82
βblockers (%	72	93.2	93.3	89	90.4	85	82	78
Aldosterone antagonists (%)	56	30.9	32.3	41.8	41.6	46	50	36

ACEI, angiotensin converting enzyme inhibitor; CRT, cardiac resynchronisation therapy; DGH, district general hospital; ICD, implantable cardiovertor defibrillator; LV, left ventricular; NYHA, New York Heart Association.

failure and LV dysfunction, and the expectation that they would require a high percentage of ventricular pacing, the implanting cardiologists deemed it inappropriate to offer right ventricular pacing alone.

Bridging the 'gap'

As eluded earlier, there is a big gap between the number of patients who are eligible for complex device therapy and the number of actual recipients.[11][12] This gap is expected to widen further, once the benefits of CRT are extrapolated to patients with less severe symptoms.[13][14] In countries like the UK, where a majority of such devices are implanted in tertiary centres, this discrepancy in supply and demand is expected to be particularly apparent. One strategy of bridging the gap would be to establish comprehensive 'heart failure programmes' which encompass CIED implantation, at a local level. This will allow early and rapid assessment of patients with suspected heart failure, and institution of appropriate pharmacotherapy where indicated, and will also identify candidates suitable for device therapy and improve referral patterns. We believe that demonstrating the success and safety of CIED implantation at a non-tertiary facility will encourage development of local comprehensive heart failure services so that anincreasing number of patients can benefit from this state-of-the-art technology.

CONCLUSION

Our retrospective 2-year single-centre experience shows that in the presence of necessary expertise, complex cardiac device implantation in patients with moderate to severe heart failure can be undertaken successfully and with a high degree of safety in the setting of a district general hospital. We hope that our study will encourage other district general hospitals to take on a more proactive role in performing complex device implantation in an attempt to increase the uptake of device therapy in the UK. This will certainly help in narrowing the gap that exists between the number of device-eligible recipients and actual recipients of such therapy.

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