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Cardiology registrars and permanent pacemaker complication rates in a district general hospital—safety and service implications

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Introduction

Permanent cardiac pacing in the district general hospital (DGH) was endorsed by the British cardiovascular society in 1987, and by 1992 a third of DGHs provided this service.[1,2] More than two decades have passed and the rates at which permanent pacemakers (PPM) are being implanted have risen substantially. Implant rates in England have increased by approximately 4% per year since 2000 to 525 PPM per million persons in 2011, but our implant rates are still much lower than those of several of our European neighbours.[3] An ageing population, greater recognition of pacing indications, and the expansion of the service for local convenience are some of the reasons for the rising implantation rates. With such increasing numbers, and newer devices and leads, it is important to get an updated perspective on the complication rates so that patients are given the correct information when they are consented. Unfortunately, beyond the data published over ten years ago from the large centre trials,[4–8] there is only one recently published report from a UK DGH.[9]

In addition to this, the current structure of specialty training in cardiology leads to most junior registrars acquiring their first experience of device implantation in the DGH. There is evidence that suggests that inexperience is positively correlated with complication rates in the short and long term.[10] Yet, there are no published data demonstrating the impact that registrar training has on patient safety and service provision in the DGH.

This prospective study, carried out over four and a half years, provides an update on the complication rates of pacemaker implantation in the DGH, and we compare this with other studies in the literature. This study also adds novel prospectively collected data to the literature on registrar complication rates and provides information on the impact that current training arrangements have on service provision.

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Methods

Chesterfield Royal Hospital, North Derbyshire, serves a population of approximately 350,000 and has two full-time cardiology consultants who perform PPM implants. Data were collected prospectively for all single- and dual-chamber pacemakers implanted between May 2008 and Nov 2012. Basic demographics, type of pacemaker (single- or dual-chamber systems), symptom and baseline ECG indications were collected. All patients were followed up at weeks 6 and 12 as part of their routine pacemaker checks and to determine if any acute complications developed. Major complications, as defined by the Heart Rhythm UK (HRUK) standards for device implantation, included atrial (A) and ventricular (V) lead displacement, pneumothorax, cardiac perforation, infections, and haematomas requiring intervention by week 12.[11] Average length of procedure, defined as the time from first cut to completion of wound closure, was also documented.

Operators were divided into two main categories. Consultants (n=2) who have implanted more than 500 PPM each, and registrars (n=8) who were all within their first two years of training and had implanted less than 20 devices each. Registrar cases were defined as all cases in which the procedure was started by the registrar, and they were all conducted under consultant supervision. Venous access was obtained either by the cephalic or subclavian route. One consultant uses subclavian only and the other uses cephalic access if available.

Prophylactic antibiotics (usually flucloxacillin 500 mg and amoxycillin 500 mg) were given by mouth before and after the procedure. The use of routine intrapocket antibiotics was routinely employed by one consultant and only after complicated procedures by the other.

Data were compiled using a Microsoft Office spreadsheet, and in-programme statistical formulae were utilised. The chi-squared (X^2) test and student's t-test were employed. A p-value of less than 0.05 was taken to be significant.

Results

Baseline characteristics

A total of 527 procedures took place over a period of four and a half years. A total of 398 pacemakers (76%) were implanted

Table 1. Presenting symptoms and underlying rhythms on ECG for patients implanted with PPM.

Most common symptoms at presentation	Most common ECG rhythm at presentation
1 Dizzy spells (64%)	1 Second and third degree heart block (40%)
2 Syncope (35%)	2 SSS/tachy-brady syndrome (27%)
3 Dyspnoea (3%)	3 Slow AF (14%)
4 Prophylactic/none (2%)	4 Bradycardia (8%)
5 Bradycardia (1%)	5 Bundle branch block (6%)
	6 Other (5%)

AF = atrial fibrillation; ECG = electrocardiogram; PPM = permanent pacemaker; SSS = sick sinus syndrome.

by consultants and 129 (24%) by trainees under supervision. Of these, 370 (70%) were dual-chamber systems, and the remaining 157 (30%) were single-chamber systems (VVI n=155, VDR n=1, AAI n=1). There was a near equal male to female ratio (1.1:1) with an average age of 79 years (SD ± 10). Table 1 shows the most common presenting symptoms and underlying rhythms on ECG.

Vascular access was achieved via the subclavian (54%) route or the cephalic (46%) route. A further breakdown shows that registrars utilised the subclavian approach more frequently than their consultants (67% vs 54%, p=0.006) (Table 2). All patients in this study were followed up at week 6 and 12. On the rare occasion where the appointment was missed, the patient had a re-scheduled appointment within a week.

Complications

Lead displacement was the most common complication with 13/526 (2.5%) for V leads and 13/371 (3.5%) for A leads overall. The V-lead displacement rate for registrars was 4/129 (3.1%), which was slightly higher than consultants at 9/397 (2.3%), but this difference was not statistically significant (p=0.60). A-lead displacement rates were again similar for both groups; 3/84 (3.6%) for registrars and 10/287 (3.5%) for consultants (p=0.97). Overall complication rates with dual-chamber PPMs were slightly higher than those for single-chamber PPMs, but the difference did not reach significance (6.3% vs 5.1%, p=0.47) (Table 3).

Infection was the next most common complication with 4/527 (0.8%) cases, followed by two cases of cardiac perforation (0.4%), and one case each of pneumothorax (0.2%) and haematoma requiring intervention (0.2%). None of these complications occurred within the registrar group. The overall complication rate for our cohort was 6.3%.

Regarding the timings of these complications, almost all of these complications were evident by week 6 of follow-up. Infections were equally as likely to occur by week 6 or 12 of follow-up (Table 4). 35 deaths (6.6%) occurred within the follow-up period, but none of these deaths were the result of complications of the implant procedure. Mortality rates were similar between the consultant and registrar group (6.8% vs 6.2%, p = not significant).

Duration of procedure

The average time taken to perform the procedure was 42 minutes. Registrars took significantly longer to perform their procedures (63 mins vs 35 mins for PPM of all types; $p < 0.0005$). Table 5 shows average durations according to type of device implanted and the access route.

Discussion

Complications – lead displacement

Compared to the 'benchmark' trials used by the HRUK standards for implantation[4-8] (Table 6), we have a higher rate of V-lead displacements. Our A-lead displacement rate of 3.5% was at the upper end of the 0.5%–4.4% range quoted in the literature.[4–8] However, the data in the literature reflect complication rates from more than 10 years ago and the trend since has been for devices to be implanted in a more elderly population with greater co-morbidities.[12] The average age of the patients in the trials quoted in the literature was about 75 years, in comparison to our slightly older cohort of 79 years. Complication rates have also been reported previously to increase with age and with co-morbidities such as left ventricular dysfunction and right ventricular dilatation.[10] It is not possible for us to comment on whether the extent of co-morbidities was similar in our study and in others.

A more recent study, carried out in 2010, reported an overall complication rate of 6.9% for 1,028 PPMs implanted.[9] The mean age of patients in this study was 77 years, with a range between 17.3 and 99.7 years. Like us, the authors of this study found a V-lead displacement rate (3.6%) that was greater than that for A-lead displacement (2.2%). They reported infection and perforation rates of 0.9% and 0.37%, respectively. They also reported high rates of pneumothorax (4.4%), which were most likely due to the almost exclusive use of the subclavian approach in their cohort. The consistent findings of higher rates of V-lead displacement may reflect a more accurate picture of the complication rates in the DGH today.

Complications: infections

Infections were limited to the surgical site in two cases and were systemic in the other two. All four patients who suffered infections ended up having their devices extracted. In the literature, the time delay before an infection becomes evident

Table 2. Comparison of the types of PPM implantations carried out by consultants and registrars.

	Consultants	Registrars	Difference	All doctors
Patient age (mean) (years)	78.5	79.9	p=ns	79
Pacemaker type	398	129		527
DDD (R)	286 (72%)	84 (65%)	p=ns	370
VVI (R)	111 (28%)	45 (35%)	p=ns	156
AAI (R)	1 (<1%)	0	p=ns	1
Access route				
Subclavian	214 (54%)	87 (67%)	p=0.006	301 (57%)
Cephalic	184 (46%)	42 (33%)	p=0.006	226 (43%)

ns = not significant; PPM = permanent pacemaker.

Table 3. Complications by experience of implanting doctor and pacemaker type.

	Consultants	Registrars		Overall
V lead	9/397 (2.3%)	4/129 (3.1%)	p = ns	13/526 (2.5%)
A lead	10/287 (3.5%)	3/84 (3.6%)	p = ns	13/371 (3.5%)
Pneumothorax	1/398 (0.2%)	0/129 (0%)	p = ns	1/527 (0.2%)
Infection	4/398 (1%)	0/129 (0%)	p = ns	4/527 (0.8%)
Perforation	2/398 (0.5%)	0/129 (0%)	p = ns	2/527 (0.4%)
Haematoma	1/398 (0.2%)	0/129 (0%)	p = ns	1/527 (0.2%)
	Dual chamber	**Single chamber**		**Overall**
V lead	7/370 (1.9%)	6/156 (3.8%)	p = ns	13/526 (2.5%)
A lead	13/370 (3.5%)	0/1 (0%)	p = ns	13/371 (3.5%)
Pneumothorax	0/370 (0%)	1/157 (0.6%)	p = ns	1/527 (0.2%)
Infection	3/370 (0.8%)	1/157 (0.6%)	p = ns	4/527 (0.8%)
Perforation	2/370 (0.5%)	0/157 (0%)	p = ns	2/527 (0.4%)
Haematoma	1/370 (0.3%)	0/157 (0%)	p = ns	1/527 (0.2%)

ns = not significant.

can extend even beyond 2 years from implant.[14] Thus, vigilance in the long term is needed. It may be worth noting that none of the four patients who had infections in our study received intrapocket antibiotics, although evidence that the routine use of antibiotic in this way is beneficial is lacking.[13–15]

A factor that could contribute to higher infection rates is age and frailty. The ages of our four patients with infections ranged from 82 and 91 years (mean 89 years) and all had significant co-morbidity. Two were bed-bound in nursing homes. There is a theoretical basis for advanced age and impaired wound healing,[16] but only some studies have found age to be a risk factor for infections.[12–15] Other variables that have been consistently associated with higher rates of infection were a previous implant and the absence of prophylactic systemic antibiotics.[12–15]

Complications: pneumothorax, perforation and haematomas

Our low rates of pneumothorax in comparison to the other studies reflect our relatively greater usage of the cephalic approach (43% in our cohort). The lack of these complications' occurrence within the registrar group may be a result of an inherent case-selection bias, with consultants opting to take on more complex cases.

Table 4. Frequency at follow-up of all major* and minor complications.

Week 6	Week 12
V-lead displacement* 13	Superficial bruising 4
A-lead displacement* 11	A-lead displacement* 2
Superficial bruising 8	Infection* 2
Stitch out of wound 4	Stitch out of wound 2
Infection* 2	Perforation* 1
Pneumothorax* 1	
Perforation* 1	
Haematoma evacuation* 1	

Operator experience

Our study results are consistent with those of a previous study by Aggarwal *et al* who found that there were no differences in complication rates between inexperienced, defined as one who had performed less than 100 procedures, and experienced operators.[5] More recently, Eberhardt *et al*. showed that operators who had performed less than 50 procedures had higher complication rates in patients who were elderly, had left ventricular impairment or right ventricular dilatation.[10] A possible explanation for the difference seen may be the different co-morbid profiles in the different studies. Another plausible explanation would be the different amount of support or supervision inexperienced operators are given in different centres. Nevertheless, our data do show that operations led by registrars working under supervision were as safe as consultant-led ones, and that the training of registrars did not appear to have any adverse impact on patient safety.

Duration of procedure and service provision

An important balance always needs to be struck between training lists and service provision. Our study provides data on the anticipated lengths of time a registrar might take to perform dual or single PPMs using different access routes, which can be factored in when planning lists for training and for service provision. Dual chamber devices take longer to implant (8–10 mins longer for consultants, and 13–29 mins longer for registrars). In addition, it is interesting to see that it took consultants slightly longer to implant all devices when they chose a subclavian approach; for registrars this approach was slightly slower for single-chamber devices. These differences in operating time may be a result of inter operator variability,

Table 6. Comparison of complications in our study and the 'benchmark' trials used for the HRUK implantation standards.

Study	Year published	V lead displacement	A lead displacement	Pneumothorax	Perforation	Infection	Haematoma requiring revision
Our study n=527		**2.5%**	**3.5%**	**0.2%**	**0.4%**	**0.8%**	0.2%
MOST[4] n=2,010	2003	0.7%	1.7%	1.5%	0.3%	0.2%	n/a
Chauhan[6] n=286	1994	1.4%	3.8%	0.7%	n/a	1.3%	0.5%
Aggarwal[5] n=587	1995	0.5%	1.6%	0.8%	n/a	1.0%	0.5%
Kiviniemi[7] n=446	1999	2.0%	4.4%	0.7%	0.7%	1.8%	n/a
Link[8] n=407	1998	1.7%	0.5%	2.0%	1.0%	0.25%	n/a

HRUK = Heart Rhythm UK.

but they do suggest that, in experienced hands, the cephalic approach does not prolong procedure length significantly and has the added advantage of negating the risk of pneumothoraces.

Limitations

The possibility of case-selection bias might result in reduced complication rates for registrars. As these were all supervised cases, the amount of consultant assistance given to the registrars may inadvertently skew the complication rates in favour of the trainee. Our data also come from a single centre and might not reflect national figures, though recently published data from a high-volume DGH mirror the relatively high lead-displacement rates seen in our study.

Conclusion

Our data provide an update on the complication rates of simple device implants in a British DGH, which remain within range previously published in the literature. Our results also show that device training can be provided in a DGH without compromising patient safety.

Table 5. Comparison of the average durations of procedures carried out by consultants and registrars.

	Dual-chamber PPM	Single-chamber PPM
Carried out by consultants		
Cephalic approach	35 mins	25 mins
Subclavian approach	40 mins	32 mins
Carried out by registrars		
Cephalic approach	73 mins	44 mins
Subclavian approach	68 mins	55 mins

PPM = permanent pacemaker.

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