J R Coll Physicians Edinb 2009; 39:113–6

The selection of pacing modalities according to NICE recommendations

[1]WK Choo, [2]L Tilling, [3]S Gupta

[1]Senior House Officer, General Medicine Department, Queens Hospital, Romford, Essex; [2]Specialist Registrar in Cardiology, Department of Cardiology, St Thomas' Hospital, London; [3]Consultant Cardiologist, Department of Cardiology, Whipps Cross University Hospital, London, UK

ABSTRACT The National Institute for Health and Clinical Excellence (NICE) recommends the use of dual-chamber pacemakers for all bradycardic patients except in a few situations. We aimed to compare our performance to the then new national guidelines. We retrospectively studied the data of all 200 patients who received single-chamber ventricular pacemakers and dual-chamber pacemakers between January 2003 and December 2005 inclusive. Pacemakers were selected based on local opinions prior to the formal adoption of NICE guidelines. In retrospect, our compliance to the guidance was 72%. Of this 72% of patients, 12% were symptomatic at one year, compared with 21% from the non-compliant group (p=0.12). In terms of mortality, 2% of the patients from the compliant group died, compared with 5% from the non-compliant group (p=0.36). Multiple factors influence clinical judgements in selecting a pacing modality. Stringent compliance with the current NICE recommendations may not necessarily reduce mortality and morbidity.

KEYWORDS Audit, National Institute for Health and Clinical Excellence, pacemaker, pacing modality

DECLARATION OF INTERESTS No conflict of interests declared.

Published online ***April 2009***

Correspondence to ***WK Choo, Department of Cardiology, Whipps Cross University Hospital, London E11 1NR, UK***

tel. ***+44 (0)7899 848138***
fax. ***+44 (0)20 8535 6690***
e-mail ***alfredwaikah@gmail.com***

BACKGROUND

The dysfunction of native pacemaker (the sino-atrial node) and atrioventricular (AV) conduction block are the most common causes of bradycardia. Single-chamber atrial pacing and dual-chamber pacing are known as 'physiological' pacing as they closely resemble cardiac physiology to maintain the dominance of sinus node activity and atrioventricular transport respectively. In theory, this should not only reduce cardiovascular morbidity and mortality but also increase quality of life.

Various studies have been conducted indicating better outcomes with dual-chamber pacing. Dual-chamber pacemakers accounted for 60% of pacemakers implanted in 2003 in the UK.[1] The National Institute for Health and Clinical Excellence (NICE) in the UK issued guidelines in February 2005 favouring the use of dual-chamber pacing in the management of patients who have symptomatic bradycardia, with a few exceptions as summarised in Table 1.[1]

TABLE 1 Indication for single- and dual-chamber pacing: a summary of NICE's recommendations on pacemaker selection

Indications for single-chamber ventricular pacing (VVI)	**Indications for dual-chamber pacing (DDD)**
Atrioventricular (AV) block with or without sick sinus syndrome • with significant comorbidities • with permanent atrial fibrillation (AF)	Atrioventricular (AV) block with or without sick sinus syndrome • without significant comorbidities • without permanent atrial fibrillation
Indications for single-chamber atrial pacing (AAI)	
Sick sinus syndrome (SSS) without AV block	

TABLE 2 A summary of locally agreed comorbidities

Reduced mobility/bed-bound
Heart failure (New York Heart Association Class 3 or 4)
Dementia (Folstein Mini-Mental Status Examination <20)
Stroke with residual symptoms
Malignancy with bad prognosis
Chronic kidney disease (glomerular filtration rate <30 ml/min)

METHODS

We retrospectively studied the data of all 200 patients who received single-chamber ventricular pacemakers (VVI) and dual-chamber pacemakers (DDD) between January 2003 and December 2005 inclusive – a period when pacemakers were selected based on local experience and opinions prior to the formal adoption of these guidelines. None of the pacemaker recipients within the stated period were excluded. This study aimed to examine our performance in comparison to the then new national guidelines and the implications for our selection of pacing modalities. Pacing notes were used for data collection. Pacing notes contain a summary of patients' medical history and information relevant to pacing. This study, based in a large district hospital in the

TABLE 3 VVI recipients (n=108): characteristics of patients who received single-chamber pacemakers*

	NICE compliant (n=62)	Non-NICE compliant (n=46)
Average age	83.7	82.0
Indications		
1) AAI indications		
SSS without AV block: no comorbidities or AF	–	25
SSS without AV block: with comorbidities	16	–
SSS without AV block: with AF	12	–
SSS without AV block: with comorbidities + AF	6	–
2) VVI indications		
AV block ± SSS with comorbidities	25	–
AV block ± SSS with AF	0	–
AV block ± SSS with comorbidities + AF	3	–
3) DDD indications		
AV block ± SSS without comorbidities or AF	–	11 (CHB) 10 (other AV blocks)
Outcomes		
Total complications	4 (6.5%)	3 (6.5%)
Symptomatic after one year	6 (9.7%)	8 (17%)
Death within one year	2 (3.2%)	2 (4.4%)

*Patients were further divided into those whose treatment was compliant with NICE guidance and those who were not. Indications according to NICE recommendations and outcomes for each of the subgroups are presented.

AF: Atrial fibrillation; AV: atrioventricular; CHB: complete heart block; SSS: sick sinus syndrome.

TABLE 4 DDD recipients (n=92): characteristics of patients who received dual-chamber pacemakers

	NICE compliant (n=81)	Non-NICE compliant (n=11)
Average age	66.4	73.3
Indications		
1) AAI indications		
SSS without AV block: no comorbidities or AF	30	–
SSS without AV block: with comorbidities	–	4
SSS without AV block: with AF	–	0
SSS without AV block: with comorbidities + AF	–	0
2) VVI indications		
AV block ± SSS with comorbidities	–	6
AV block ± SSS with AF	–	1
AV block ± SSS with comorbidities + AF	–	0
3) DDD indications		
AV block ± SSS without comorbidities or AF	34 (CHB) 17 (other AV blocks)	–
Outcomes		
Total complications	6 (7.4%)	1 (9.1%)
Symptomatic after one year	11 (14%)	4 (36%)
Death within one year	1 (1.2%)	1 (9.1%)

northeast of London, received approval from the local ethics committee.

Locally agreed comorbidities were taken into account in this study, as illustrated in Table 2. If one or more of these were present, we considered that a dual-chamber pacemaker would not add prognostic benefit to patients' quality of life.

Patients were divided into two separate arms of study, the VVI and the DDD arms. All leads inserted were passive. No patients at our centre underwent septal pacing, so all ventricular leads implanted pace the ventricular apex. The primary endpoint was to examine the characteristics of the pacemaker recipients. The secondary endpoints were to compare mortality and morbidity between the compliant and non-compliant groups. The elimination of bradycardia-related symptoms (i.e. chest pain, breathlessness, palpitations, dizziness, syncope and fatigue) at one year indicates success in symptom control.

The student t-test was used to compare parametric age group data. Fisher's exact test was used to compare all outcomes between recipients who were compliant and those who were not. All analyses were conducted according to 'intention-to-treat'.

RESULTS

The indications for pacemaker insertion, comorbidities and outcomes are shown in Tables 3 and 4. Approximately half of those who received VVI pacemakers had sick sinus syndrome (SSS) without AV nodal involvement. Most patients who received DDD pacemakers had complete heart block.

NICE recommends single-chamber atrial pacemakers (AAI) to patients with SSS without AV nodal involvement. We considered that it was more appropriate to insert dual chamber pacemakers, which not only allow atrial pacing alone (AAI) but also pace the ventricles if this group develops AV nodal disease at a later stage. Invasive

TABLE 5 Symptoms experienced in the first year*

	VVI recipients		DDD recipients	
	NICE compliant	Non-NICE compliant	NICE compliant	Non-NICE compliant
Dizziness	2	4	2	1
Syncope	2	1	1	0
Palpitations	0	2	1	1
Breathlessness and chest pain	0	1	3	2
Fatigue	0	0	1	0
Unknown	2	0	3	0
Total	**6**	**8**	**11**	**4**

*Symptoms described by patients in different subgroups at one year. Numbers in this table represent number of patients.

electrophysiological studies have demonstrated abnormal AV conduction in 57–67% patients with SSS.[2–4] We enrolled the 25 patients with SSS who received VVI pacemakers into the non-compliant group. Likewise, we classify the 30 who received DDD pacemakers as compliant. Single-chamber ventricular pacemakers rather than DDD-pacing would still be preferred if patients have comorbidities or sustained episodes of atrial fibrillation.

Single-chamber ventricular pacing

A total of 62 patients (57%) received VVI pacing in compliance with NICE recommendations, but 46 (43%) did not. The mean age between the compliant and the non-compliant groups did not differ significantly (p=0.21).

Four patients in the compliant group experienced complications, compared with three in the non-compliant group (p>0.05). Complications seen were pneumothorax, haematoma and intra-procedure arrhythmia. Persisting symptoms experienced at one year by VVI recipients are illustrated in Table 5. Dizziness was the predominant complaint in both subgroups.

Two cardiac-related deaths occurred in each group. The two deaths in the compliant group were due to congestive cardiac failure. In the non-compliant group, one patient died of myocardial infarction, while the other died of pulmonary embolus 25 days post-pacemaker insertion.

Dual-chamber pacing

A total of 81 patients (88%) received DDD pacemakers in agreement with NICE recommendations, but 11 patients (12%) did not. Age difference between the subgroups was not significant (p=0.11).

TABLE 6 Comparison between those who were NICE compliant and those who were not

	NICE compliant n=143	Non-NICE compliant n=57
Average age	73.9	80.3
Symptomatic after one year	17 (11.89%)	12 (21.05%)
Death within one year	3 (2.10%)	3 (5.26%)

Six patients in the compliant group experienced complications, compared with one in the non-compliant group (p>0.05). Complications seen were pneumothorax and intra-procedure arrhythmia. Persisting symptoms experienced at one year by DDD recipients are illustrated in Table 5. Breathlessness was the predominant complaint in both subgroups. Only one cardiac-related death was seen in each group, one from myocardial infarction and the other from heart failure.

Comparison with NICE recommendations

In retrospect, 143 (72%) of our patients were compliant with NICE's recommendation. As illustrated in Table 6, fewer patients in the NICE-compliant group complained of persisting symptoms after one year, 12% vs 21% from the non-compliant group. This difference was not statistically significant: odds ratio (OR) 0.56, 95% confidence interval (CI) 0.29–1.11; p=0.12. Although fewer deaths were observed in the compliant group, this again was not statistically significant: OR 0.40, 95% CI 0.08–1.92; p=0.36. Although age was not a consideration when selecting a device, younger patients (mean age of 74) were more likely to receive a pacemaker according to NICE recommendations than older patients (mean age of 80), p=0.001. We also found that older patients (mean age of 83 years) were more likely to be given a VVI pacemaker compared with younger ones (mean age of 67); p<0.0001.

DISCUSSION

We present a retrospective study of 200 pacemaker recipients, with follow-up on mortality and symptom control. We believe this to be the first report comparing local practices to NICE guidelines.

A total of 72% of patients received their pacemakers in accordance with NICE recommendations. No statistically significant differences were observed in the outcomes between those who complied with NICE guidelines and those who did not.

Although our sample size may be small, we consider it to be sufficiently large to represent the population of pacemaker recipients in district hospitals. The resolution of symptoms and the small numbers of complications and fatalities reflect the advances made in pacemaker technology and operator technique. We believe the low

mortality rate and incidence of complications to be similar to that in other district hospitals.[5,6]

Selections that were not NICE-compliant should not have incurred a higher cost since a larger proportion of non-NICE compliant patients received the cheaper VVI pacemaker instead of the DDD. An in-depth cost analysis is needed to confirm this deduction.

Like any retrospective study, the major limitation in this study is selection bias. Patients with SSS without AV node involvement were considered more appropriate to receive dual-chamber pacemakers. Single-chamber atrial pacemaker recipients could have been analysed as a separate group. Other limitations include the difficulty in determining whether the observed symptoms were due to the inability of pacemakers to control the symptoms or symptoms resulting from other comorbidities.

To date, only a handful of trials have been performed on large cohorts of patients. A meta-analysis of four parallel randomised control trials (MOST, CTOPP, PASE and Wharton et al.) did not show a statistically significant reduction in mortality in the dual-chamber group compared with the single-chamber group: OR 0.94, 95% CI 0.80–1.12.[7–11]

A meta-analysis by Dretzke et al. found a statistically significant reduction in symptoms with dual-chamber pacing as opposed to single-chamber ventricular pacing, specifically dizziness, fatigue, breathlessness, chest pain and palpitation.[12]

CONCLUSION

The decision to insert single- or dual-chamber pacemakers is often multifactorial; individual physicians may have different opinions and practices. The 28% of our patients who were not NICE-compliant did not fare any worse than those who were. No statistically significant differences were observed. We conclude that stringent compliance with the current NICE recommendations may not necessarily reduce mortality and morbidity. We suggest a larger, prospective reaudit to evaluate current practice in the era of NICE. This could also assess the impact of costs in the selection of pacemakers – something that this study did not address and that may facilitate the next appraisal of the current NICE recommendations.

Acknowledgement We wish to record our thanks to Prof. Malcolm Law for his guidance in the statistical analyses, Dr Shilpa Kanzaria, Dr Orestes Couppis, Dr John Dabis and Dr Gemma Palmer for their part in data collection, and the pacemaker technicians at Whipps Cross University Hospital.

REFERENCES

1 National Institute for Health and Clinical Excellence. *Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block.* London: NICE; 2005. Available from: http://www.nice.org.uk/Guidance/TA88/Guidance/pdf/English

2 Vallin H, Edhag O. Associated conduction disturbances in patients with symptomatic sinus node disease. *Acta Med Scand* 1981; 210:263–70.

3 Cheng TO, Ertem G. Is 'sick sinus syndrome' a sickness of sinus node alone? *Circulation* 1971; 44(Suppl 2):150.

4 Narula OS. Atrioventricular conduction defects in patients with sinus bradycardia: analysis by His bundle recordings. *Circulation* 1971: 44:1096–110.

5 Eberhardt F, Bode F, Bonnemeier H et al. Long term complications in single and dual chamber pacing are influenced by surgical experience and patient morbidity. *Heart* 2005; 91:500–6.

6 Bagherzadeh A, Emkanjoo Z, Haghjoo M et al. Complications and mortality of single versus dual chamber implantable cardioverter defibrillators. *Indian Pacing Electrophysiol J* 2006; 6:75–83.

7 Lamas GA, Lee KL, Sweeney MO et al. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction. *N Engl J Med* 2002; 346:1854–61.

8 Lamas GA, Orav J, Stambler BS et al. Quality of life and clinical outcomes in elderly patients treated with ventricular pacing as compared with dual-chamber pacing. *N Engl J Med* 1998; 338:1097–104.

9 Connolly SJ, Kerr CR, Gent M et al. Effects of physiologic pacing versus ventricular pacing on the risk of stroke and death due to cardiovascular causes. *N Engl J Med* 2000; 342:1385–91.

10 Kerr CR, Connolly SJ, Abdullah H et al. Canadian trial of physiological pacing: effects of physiological pacing during long-term follow-up. *Circulation* 2004; 109:357–62.

11 Wharton JM, Sorrentino RA, Campbell P et al. Effect of pacing modality on atrial tachyarrhythmia recurrence in the tachycardia-bradycardia syndrome: preliminary results of the Pacemaker Atrial Tachycardia Trial. *Circulation* 1998; 98(suppl. I):1-494.

12 Dretzke J, Toff WD, Lip GYH et al. Dual chamber versus single chamber ventricular pacemakers for sick sinus syndrome and atrioventricular block. *Cochrane Database Syst Rev* 2004; 2CD003710.