Atrial pacemaker leads compared

MARTIN M. MASTERSON, MD; JAMES D. MALONEY, MD; E. MURAT TUZCU, MD; BRUCE L. WILKOFF, MD; ATILA EMRE, MD; GABRIEL VANERIO, MD; TONY W. SIMMONS, MD; VICTOR A. MORANT, MD; LON W. CASTLE, MD

■ In order to analyze the impact of different polarity and electrode designs on the acute pacing and sensing characteristics of pacemaker leads, 80 patients with complete heart block or sinus node dysfunction undergoing pacemaker implantation received eight different leads from five manufacturers. Once the leads were positioned, volt and current thresholds, P wave, peak-to-peak, and slew rate were assessed prospectively. There was no statistically significant difference between acute pacing thresholds, sensing characteristics, or unipolar and bipolar pacing thresholds. Active fixation leads allow atrial mapping and lead placement in areas generally inaccessible to tined tip leads. This is an advantage, especially for patients with a history of open heart surgery.

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PROPER FUNCTION of implanted pacemakers depends on lead stability, adequate sensing of spontaneous electrical activity, and satisfactory myocardial stimulation thresholds. Sensing is especially critical in the atrium because of the low amplitude of its intracardiac electrical activity. The search for the ideal electrode continues, with the development of new designs and materials.[1–3]

It is now generally accepted that unipolar and bipolar sensing and pacing thresholds are comparable, but the bipolar configuration offers better signal-to-noise discrimination with less electromagnetic interference and muscle stimulation.[4–7] In addition, developments such as the active fixation (screw-in) electrode and the passive fixation electrode with tines close to the tip have substantially reduced the possibility of dislodgment.[7–11] However, the effects of active fixation on acute and chronic thresholds have not been studied extensively.[12]

We analyzed eight commercially available modern bipolar lead types to determine their comparative sensing and pacing characteristics in the clinical setting.

METHODS

Patients

This prospective study involved 80 consecutive patients who underwent atrial and ventricular lead implantation because of syncope, complete heart block, or both. Eleven patients entered the study following open heart surgery (OHS). The radiation exposure for ventricular and atrial lead placement, and the total time required for implantation were recorded.

Pacing system analyzer

All pacing thresholds were assessed with the Medtronic 5311 AV Pacing System Analyzer (PSA) at a

From the Department of Cardiology, Section of Electrophysiology and Pacing, The Cleveland Clinic Foundation.

Address reprint requests to J.D.M., Department of Cardiology, Section of Electrophysiology and Pacing, The Cleveland Clinic Foundation, One Clinic Center, 9500 Euclid Avenue, Cleveland, Ohio 44195.

TABLE 1
LEAD CHARACTERISTICS

	Distal electrode	Proximal electrode		
Manufacturer and model	Shape	Area (mm^2)	Shape	Area (mm^2)
Medtronic Inc. 4016-53*	Helical screw electrically active	8	Ring	46
Intermedics Inc. 480-01*	Solid ring tip, helical screw	10	Ring	50
Cardiac Pacemakers Inc. 4266*	Porous wire mesh, helical screw	10	Ring	35
Teletronics Inc. 0303-62*	Solid ring tip, helical screw electrically active	12	Ring	49
Cardiac Pacemakers Inc. 4270	Porous wire mesh	8	Ring	49
Cordis Corp. 3297-49	Macroporous tip	8.8	Ring	57.2
Medtronic Inc. 4512-53	Target tip, microporous platinized platinum	8.4	Ring	52
Intermedics Inc. 492-01	Solid ring tip	10	Ring	57

*Active fixation lead

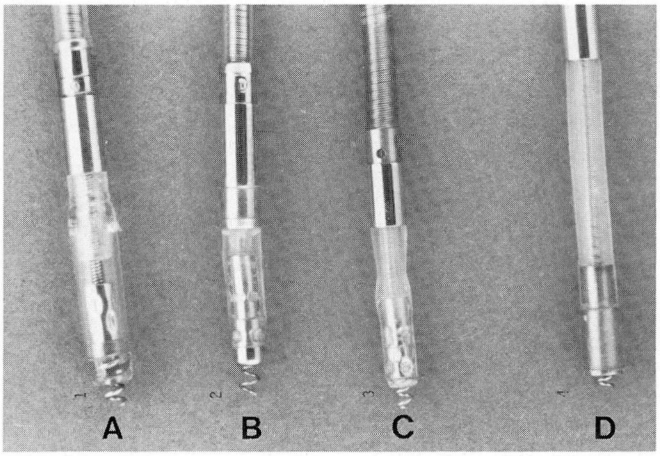

FIGURE 1. Active fixation leads. A, Medtronic Inc 4016-53; B, Intermedics Inc 480-01; C, Cardiac Pacemakers Inc 4266; D, Teletronics Inc 0303-62.

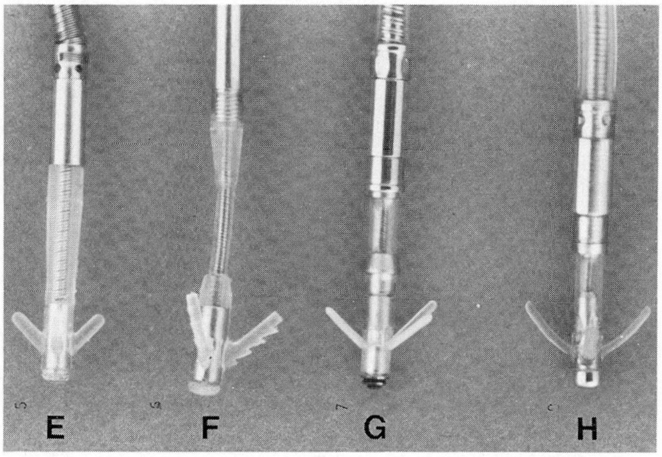

FIGURE 2. Passive fixation leads. E, Cardiac Pacemakers Inc 4270; F, Cordis Corp 3297-49; G, Medtronic Inc 4512-53; H, Intermedics Inc 492-01.

pulse width of 0.5 ms. The P wave was obtained from the permanent atrial lead and measured directly from a Gould chart recorder with band pass filtering for 30 Hz to 300 Hz. Satisfactory electrode position was shown by a P wave greater than 2 mV and the lack of any significant (less than 0.5 mV) R wave in the unipolar mode.

The PSA was then used to assess the P wave; the device was filtered with sensitivity calibration based on a 10-ms sine wave (simulated P-wave), with band pass filtering at 50 Hz to 350 Hz and a central frequency of 100 Hz with a cutoff amplitude of 3 Db and input impedance of 50,000 ohms. The peak-to-peak P-wave amplitude was analyzed by assessing the unfiltered signal, and represented the actual peak-to-peak voltage of the detected atrial signal (measurable range 0.5 mV to 25.4 mV with a resolution of 0.2 mV).

The slew rate of the P wave was assessed using the unfiltered signal, and represented the rate of change of slope of the detected signal in volts per second (measurable range 0.1 V/s to 7.5 V/s with a resolution of 0.01 V/s).

All patients were assessed in the unipolar mode using a temporary indifferent electrode (Medtronic 5803, Medtronic Inc) with a tip surface area of 281 mm^2. The electrode was connected to the positive pole of the PSA and the tip was positioned in the pectoral pocket. Patients were assessed in the bipolar mode immediately afterward.

Leads

Eight lead types from various manufacturers were assessed. Each type of lead was implanted in 10 patients. The characteristics of the leads are compared in *Table 1* and *Figures 1* and *2*.

TABLE 2
PACING AND SENSING PARAMETERS AT IMPLANTATION

Manufacturer and model	Threshold (V)		Sensing: P wave (mV)		Sensing: Peak P (mV)		Sensing: SR (V/s)	
	UNI	BI	UNI	BI	UNI	BI	UNI	BI
Medtronic Inc. 4016-53	0.6	0.7	2.4	2.8	3.4	3.5	0.8	0.8
Intermedics Inc. 480-01	0.8	0.9	3.2	3.0	4.3	3.8	0.78	0.69
Cardiac Pacemakers Inc. 4266	0.9	0.9	2.6	2.7	3.4	3.3	0.78	0.55
Teletronics Inc. 0303-62	0.7	0.8	2.1	2.1	2.8	2.9	0.4	0.5
Cardiac Pacemakers Inc. 4270	0.8	0.7	2.4	2.6	3.3	3.8	0.9	0.9
Cordis Corp. 3297-49	0.8	0.9	2.7	2.8	3.5	3.8	0.7	0.7
Medtronic Inc. 4512-53	0.6	0.6	2.7	3.0	3.3	3.6	0.6	0.7
Intermedics Inc. 492-01	0.7	0.7	2.8	3.1	3.2	4.2	0.6	0.7

Peak P = peak-to-peak P wave, SR = slew rate, UNI = unipolar, BI = bipolar

Statistical analysis

Student t-test was used to determine differences in paired data for the same lead. Analysis of variance was used to assess differences in parameters for different leads. A *P* value of less than 0.05 was regarded as significant.

RESULTS

Atrial pacing threshold

The pacing thresholds for each of the eight leads show that mean unipolar *v* bipolar pacing thresholds were not significantly different, nor were there significant differences between lead types. When active and passive fixation leads were compared in unipolar and bipolar modes, no significant differences in the pacing thresholds were noted.

Among patients who received active fixation leads (*Table 1*), those with a history of recent open heart surgery demonstrated higher pacing thresholds in both unipolar and bipolar modes than those who had not undergone heart surgery (1.18 V *v* 0.64 V). Even when the patients with recent heart surgery were excluded from analysis, no significant differences in pacing thresholds were demonstrated between different leads and between active and passive fixation leads.

SENSING CHARACTERISTICS

P wave

The mean P wave for each lead type did not differ significantly when assessed in unipolar and bipolar modes except for the Intermedics 492-01 lead, which had significantly larger P waves in the bipolar mode than in the unipolar mode (3.1 mV *v* 2.75 mV, P = 0.05). The P wave amplitudes in patients with a history of open heart surgery were similar to those who had not had surgery.

Patients with active fixation leads had similar P wave amplitudes compared to patients with passive fixation leads when assessed in unipolar and bipolar modes.

Slew rate

Among the various leads, there were no significant differences in slew rate (*Table 2*). The rates were similar in patients with active and passive fixation leads. Patients with a history of recent open heart surgery had significantly lower slew rates than the patients without a history of open heart surgery (0.39 V/s *v* 0.73 V/s, *P* = 0.0003).

Peak-to-peak P wave

The mean peak-to-peak P wave, assessed for each lead in unipolar and bipolar fashion, was not significantly different except with the Intermedics 492-01, which had a significantly higher peak-to-peak P wave amplitude detected in the bipolar mode. Patients with a history of recent open heart surgery had significantly lower peak-to-peak P wave amplitudes (2.5 mV *v* 377 mV, *P* = 0.001) than patients who had not undergone heart surgery. P wave amplitudes for patients receiving active fixation leads were not significantly different from those receiving passive fixation leads.

Radiation and total implant time

The radiation exposure time (18.6 minutes *v* 21.6 minutes) and the total implant time (168 minutes *v* 183 minutes) for the implantation of active *v* passive fixation leads in the atrium and ventricle were not significantly different.

DISCUSSION

Appropriate atrial pacing lead selection for permanent pacemaker therapy warrants consideration of acute and long-term lead stability, and of sensing and pacing characteristics. The development of tined atrial J passive fixation leads and screw-in active fixation leads significantly reduced the dislodgment of implanted atrial leads.[11] Dislodgment rates ranging from 0% to 4% were reported recently.[9,11] Dislodgment was equally likely with screw-in active fixation leads and tined fixation leads, even in patients who had undergone open heart surgery.[9]

The comparison of various electrode designs (solid cylindrical tip, porous wire mesh tip, macroporous platinum iridium tip, microporous platinized platinum target tip, and helical screw tip) demonstrated no significant differences for acute pacing thresholds. This is consistent with most studies,[3,13] but a few suggest that acute and chronic stimulation thresholds with porous electrodes are superior to those with solid-tip electrodes.[14,15]

Active fixation screw-in leads allow atrial mapping and lead placement in areas generally inaccessible to tined tip leads, but this does not significantly enhance pacing thresholds. Our study detected no significant differences between active and passive fixation leads for acute myocardial stimulation assessment—a finding that is in agreement with previous reports.[9] On the other hand, in our series, patients with a history of recent open heart surgery (all of whom were implanted with active fixation leads because of atrial appendage amputation) had significantly higher pacing thresholds than nonsurgical patients who were implanted with active fixation leads.

The effort to improve sensing of low amplitude atrial electrical activity has led to several technological innovations and changes in the design of electrode tips. Porous wire mesh, macroporous, and microporous platinized platinum tips have increased surface areas that should result in better sensing. However, when these leads were compared with the solid-tip electrode, there was no evidence of superior performance for any of the sensing parameters assessed. Furthermore, sensing capability at acute implantation was similar in patients with active and passive fixation leads.

The comparison of unipolar *v* bipolar modes for the same lead type and between different leads showed no significant differences in ability to sense the P wave or the slew rate; the exception was the Intermedics 492-01 lead, which had superior bipolar sensing of P wave and slew rate. Patients with a history of recent open heart surgery, all of whom were implanted with active fixation leads, had significantly lower slew rates and peak-to-peak P waves but no other significant P-wave differences.

Other evaluations of pacing and sensing thresholds in patients who have had open heart surgery have demonstrated acute sensing thresholds similar to those reported in our series.[16,17]

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