Durability of bipolar coaxial endocardial pacemaker leads compared with unipolar leads

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■ **BACKGROUND** The coaxial design allows for thinner bipolar endocardial pacemaker leads, but recent reports have suggested a higher incidence of failure for this sophisticated configuration.

■ **OBJECTIVE** To compare the long-term survival of bipolar coaxial and unipolar leads.

■ **METHODS** Retrospective follow-up.

■ **RESULTS** Between January 1, 1980 and June 30, 1991, 1142 bipolar coaxial leads and 1181 unipolar leads were implanted at the Cleveland Clinic. The mean follow-up was 33 ± 32 months (range 1 to 138 months). Ten bipolar coaxial leads failed (0.88%), as did 9 unipolar leads (0.76%). At 5 years the cumulative survival was 98.6% for both types of leads; however, at 10 years the survival of bipolar coaxial leads was only 92.4% compared with 98.6% of unipolar leads ($P = .03$; relative risk 2.7, 95% confidence interval = 1.1 to 6.9).

■ **CONCLUSIONS** The sophisticated design of bipolar coaxial leads could be the cause of their increased vulnerability. The benefit-to-risk ratio of this design should be prospectively reevaluated.

■ INDEX TERMS: PACEMAKER, ARTIFICIAL; ELECTRODES, IMPLANTED; EQUIPMENT FAILURE ■ CLEVE CLIN J MED 1994; 61:25–28

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THE RELIABILITY of long-term cardiac pacing therapy is well established.[1-3] However, the introduction of new technologies should always raise concern regarding long-term safety.

Endocardial pacing leads have undergone a remarkable evolution in the last 15 years, reflected in complex structural designs, active or passive fixation mechanisms, and new insulation and conductor materials.[4] The bipolar coaxial design with polyurethane insulation has gained wide acceptance for dual-chamber pacing because it facilitates the insertion of two leads via a small vein. Coaxial leads have permitted the widespread use of the bipolar configuration. Bipolar sensing is superior to unipolar sensing because unipolar systems tend to oversense inappropriate intracardiac and extracardiac potentials, resulting in potentially dangerous inhibition of the pacemaker stimulation.[5-9]

Recent reports have raised concerns about the durability of bipolar coaxial leads.[4,10] An unexpect-

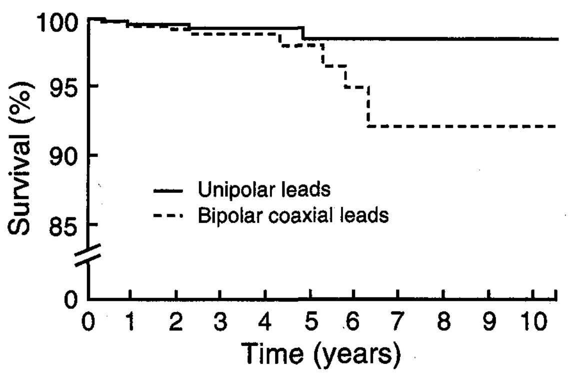

FIGURE 1. Kaplan-Meier estimate of long-term survival of bipolar coaxial and unipolar endocardial pacemaker leads. At 10 years, 98.6% of the unipolar leads and 92.4% of the bipolar coaxial leads were free of failure ($P = .03$; relative risk 2.7).

edly high incidence of lead failure was found, which was reportedly due to insulation breakdown. However, other investigators have reported that the durability of bipolar coaxial leads was comparable to that of unipolar leads.[1,11]

We examined the long-term survival of endocardial bipolar coaxial pacing leads compared with a control group of contemporary unipolar pacing leads. In addition, we analyzed the different insulation materials and lead components as potential predictors for lead failure.

METHODS

Study population

We reviewed the medical records of all patients who underwent endocardial pacemaker lead implantation at The Cleveland Clinic Foundation between January 1, 1980 and June 30, 1991. Demographic and follow-up data were obtained from the medical records and from questionnaires completed by the patients and their private physicians. These were supplemented, when necessary, with direct contact with patients by mail or phone.

All leads for which at least 1 month of follow-up was available were included in the study. Ten different manufacturers and 123 models were represented. One hundred and twenty-one bipolar noncoaxial (side-by-side) leads were excluded.

In total, 2323 endocardial pacing leads were included, comprising 1142 bipolar coaxial leads (49%) and 1181 unipolar leads (51%). Of the bipolar coaxial leads, 493 (45%) were implanted in the right atrium and 649 (55%) were implanted in the right ventricle. Of the unipolar leads, 525 (44%) were implanted in the atrium and 656 (56%) were implanted in the ventricle. The lead was inserted via puncture of the subclavian vein in 2044 (88%), and a cephalic "cut-down" approach was used in 279 (12%). The insulation material was polyurethane in 1325 (57%), silicone in 882 (38%), and of mixed composition in 116 (5%).

Definitions

Lead failure was defined as failure of either the conductor or the insulation, as determined by a chest roentgenogram or direct intraoperative observation or electrical testing. All leads were followed up until the study ended, the patient died or was lost to follow-up, or the lead failed or was discontinued for reasons unrelated to lead failure (infection, dislodgment, pacemaker-lead incompatibility, or electrical abandonment of atrial leads in atrial fibrillation).

Statistical methods

Values are presented as the mean ± 1 standard deviation. Baseline comparisons were made by means of either the *t* test or chi-square test, as appropriate. The survival of each group of leads was assessed by the Kaplan-Meier method. The generated curves were compared by the log-rank test. A *P* value less than .05 was considered significant.

RESULTS

The mean follow-up was 33 ± 32 months. Ten of 1142 bipolar coaxial leads (0.88%) failed, 3 due to conductor fracture and 7 due to insulation failure. In contrast, 9 of 1181 unipolar leads (0.76%) failed, 2 due to conductor fracture and 7 due to insulation failure. The cumulative survival of bipolar coaxial leads was 98.6% at 5 years (95% CI = 95% to 99%) and 92.4% at 10 years (95% CI = 82% to 96%). For unipolar leads the cumulative survival was 98.6% (95% CI = 97% to 99%) at both 5 and 10 years. The survival of bipolar coaxial leads at 10 years was significantly lower than the survival of unipolar leads ($P = .03$; relative risk = 2.7, 95% CI = 1.1 to 6.9) (*Figure 1*).

There was no significant difference in the proportion of lead failures due to insulation breakdown or conductor fracture comparing bipolar coaxial with unipolar leads. Among the bipolar coaxial leads that failed, five had polyurethane, three had silicone, and two had mixed-composition insulation. Among the unipolar leads that failed, three had polyurethane and six had silicone insulation (P = NS). The route of access was not associated with lead failure in either group.

DISCUSSION

The definitions of lead failure used in different studies are critical for adequate assessment and comparison of results.[12] In this study, we considered only documented structural or material-related failures, not dislodgment or exit block. The total incidence of failure in this large series is similar to that reported in studies that used comparable definitions.[1,3]

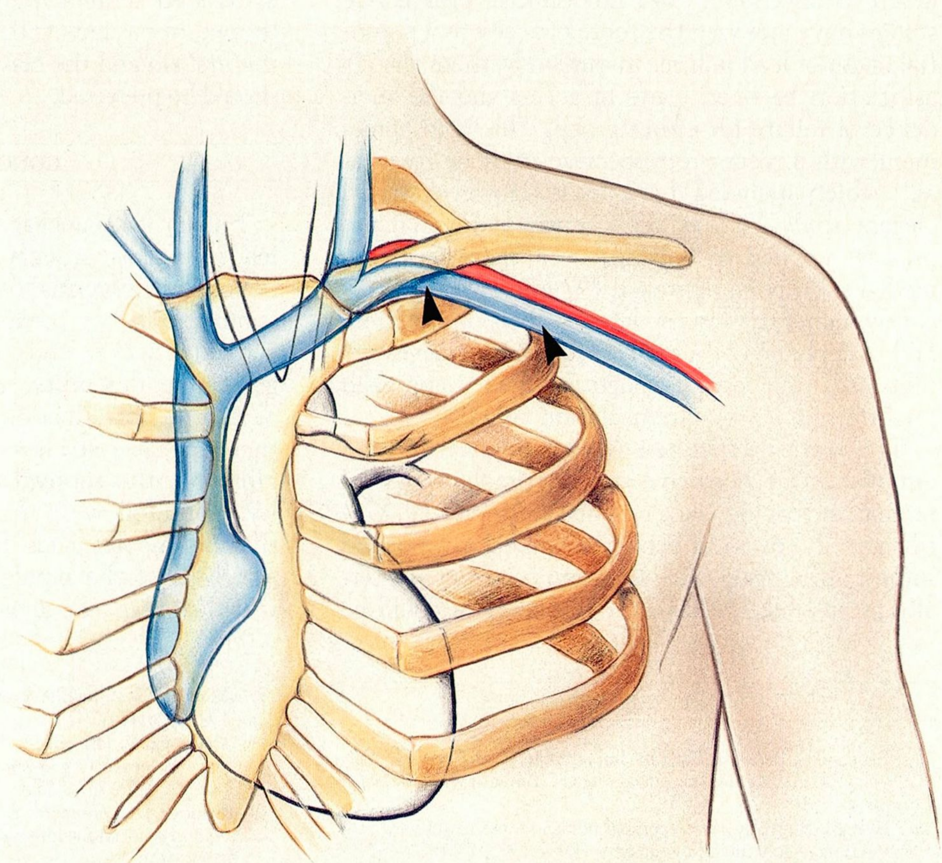

FIGURE 2. Insertion of a pacemaker lead via the subclavian vein. A lead inserted via a medial approach (medial arrow) may be exposed to excessive pressure as it is pinched between the clavicle and the first rib, and this approach may be associated with a higher rate of failure than a more lateral approach (lateral arrow). However, the lateral approach is associated with a higher incidence of pneumothorax.

Our data suggest a higher incidence of failure for bipolar coaxial leads than for unipolar leads. Bipolar coaxial leads showed a durability similar to that of unipolar leads until 5 years after implantation; thereafter, they had a significantly higher incidence of failure. The reasons for this increased vulnerability are not clear. The materials used in the insulation and conductor were similar for both groups of leads. Furthermore, the similar proportion of failed leads with polyurethane, silicone, or mixed-composition insulation in both groups does not implicate the material *per se* in the different long-term survival.

The differences in lead survival should therefore be attributed to the design and construction of bipolar coaxial leads. Coaxial leads have three or four times more parts, joints, and connections than unipolar leads,[4] and they can develop an electrical short circuit between the inner and the outer conductor coils if the inner insulation is compromised or damaged. Although approximately three leads failed due to insulation failure for every one that failed due to conduction fracture, the ratio was similar for both types of leads. The insulation can potentially be damaged by chronic excessive pressure applied to the lead body at the level of the anchoring sleeve or by a clamping effect between the clavicle and the first rib when the subclavian insertion technique is used, or both.

The evidence linking insertion via subclavian puncture with an increased incidence of insulation failure is anecdotal.[13] No randomized, prospective studies have analyzed the route of access as a potential cause of lead failure. In our study, there was no association between route of access and the incidence of failure for either group. This is in agreement with a recent retrospective study by Irwin et al,[14] which included 1252 leads. However, in an elegant study, Fink et al[15] recently found that the pressure applied to a balloon transponder in the medial subclavian approach (97 mm Hg) is significantly higher than in the lateral subclavian (42 mm Hg) or cephalic (27 mm Hg) approaches, suggesting that leads implanted through the medial approach might be more prone to insulation failure.

The approach that best avoids complications and diminishes the operative time for implantation of permanent pacing leads remains controversial. Until more information becomes available, we would suggest attempting the subclavian puncture as laterally as possible (*Figure 2*). However, this could be associated with a higher incidence of pneumothorax. In patients with a very small space between the first rib and the clavicle, the cephalic approach should be preferred.

CONCLUSIONS

Bipolar leads appear to be preferable to unipolar leads in most aspects: they reduce "cross-talk," skeletal myopotential oversensing, and local muscle stimulation, they produce a greater depth of pulse generator pocket, and they are compatible with programming flexibility and special pacing systems. With the introduction of polarity programming, there appears to be less reason to use unipolar leads. However, the survival of bipolar coaxial leads in long-term follow-up studies seems to be worse than that of unipolar leads. For this reason, the benefits and risks of the bipolar coaxial design should be reevaluated in a large prospective randomized study.

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