

An Analysis of Costs and Complications of Monophasic and Biphasic Implantable Cardioverter Defibrillators

Linette R. Klevan, RN, BS; Martha M. Tenzer, BA; Robert C. Bernstein, MD; and John M. Herre, MD

Abstract

Newer technology may be associated with higher treatment costs. However, if this technology can reduce the complications of therapy, improve device reliability, and decrease the costs of follow-up, then it may reduce overall treatment costs. We compared the costs and complications of implantable cardioverter defibrillator therapy using pulse generators with monophasic and with biphasic waveforms. Direct hospital costs of several implantable cardioverter defibrillation systems were analyzed over the lives of the systems. Early and late complications were tracked, and overall patient survival was analyzed. Long-term survival did not differ between patients receiving newer technology and patients receiving older technology. However, long-term costs of care were lower in patients with newer, often investigational, devices. Careful use of investigational devices and newer technology may reduce the costs of implantable cardioverter defibrillator therapy. Reimbursement policies should favor the use of investigational technology when costs savings can be achieved.

(*Am J Man Care* 1995;1:35-40)

The implantable cardioverter defibrillator (ICD) prevents sudden cardiac death in patients with a history of sustained ventricular arrhythmia.^{1,2} Since its introduction in the early 1980s,³ ICD technology has undergone a variety of improvements, including the addition of extensive programmability and antitachycardia pacing, pulse-generator size reduction, increased longevity, enhanced memory, biphasic shocking waveforms, and nonthoracotomy implantation. The decreased morbidity

and mortality of patients receiving nonthoracotomy implantation with transvenous leads has led to a dramatic increase in device utilization. Because of the high costs of pulse generators, lead systems, and implantation procedures, ICD therapy represents a major healthcare expenditure.^{4,6} Transvenous systems have replaced thoracotomy systems for virtually all procedures with the exception of implantation with concomitant open heart surgery. Previous studies have demonstrated that ICD implantation via a transvenous approach is less costly than implantation via a thoracotomy approach.⁷

Despite the improved defibrillation thresholds of devices with biphasic waveforms, pulse generators with monophasic waveforms are still available, often at markedly reduced prices.⁸ Recently, the Health Care Financing Administration (HCFA) and commercial third-party payers have decided to deny reimbursement for implantation of ICD devices undergoing clinical investigation, a policy that could slow the development of new technology.

The purpose of this study was to examine the cost-effectiveness and complications of monophasic and biphasic ICD pulse generators with transvenous leads and the role of third-party payers in the development of new ICD technology.^{9,10}

... METHODS ...

Patient Population

All patients referred to Sentara Norfolk General Hospital with cardiac arrest or sustained ventricular tachycardia (VT) not attributed to a correctable cause were considered for ICD implantation. Consecutive patients (n = 245) who received a transvenous ICD system between March 1991 and March 1995 were included. All patients underwent baseline electrophysiologic study in the absence of antiarrhythmic agents. Patients with a history of sustained ventricular arrhythmia, but without inducible VT, underwent ICD implantation. If sustained monomorphic VT was

From the Department of Internal Medicine, Eastern Virginia Medical School, and the Cardiac Research Department, Sentara Norfolk General Hospital, Norfolk, VA

Address correspondence to: Linette R. Klevan, RN, Cardiac Research Department, Sentara Norfolk General Hospital, 600 Gresham Drive, Norfolk, VA 23507

induced with programmed ventricular stimulation during the baseline study, pharmacologic testing was performed. If clinically indicated, patients who continued to have inducible VT despite drug therapy or who, in the opinion of the electrophysiologist, would be better treated with ICD therapy underwent ICD implantation. Long-term results, including follow-up and management of late failures and other complications, were evaluated.

ICD Types

Pulse generators with only monophasic waveforms were implanted with transvenous lead systems in 129 patients. Monophasic pulse generators included Cardiac Pacemakers, Inc (CPI) models 1550, 1555, and 1600 (n = 81); and CPI models 1700 and 1705 (n = 48). Pulse generators with biphasic waveforms were implanted in 116 patients and included the CPI model 1625 (n = 20), CPI Model 1715 (n = 2), Ventritex Cadence model V100 and 110 (n = 79), and Medtronic model 7219 (n = 15) (Table 1). CPI Endotak 60 and 70 series transvenous leads were used in all patients receiving CPI pulse generators, as well as in 64 patients receiving Ventritex pulse generators. The Ventritex TVL lead system was used in 15 patients with Cadence model V100 and 110 pulse generators. The Medtronic Transvene lead system was used in all patients receiving model 7219 pulse generators.

All patients in this study received either clinically available systems or systems not yet approved by the US Food and Drug Administration (FDA), although all the systems currently have FDA approval. Of the systems with monophasic pulse waveforms, 128 were implanted prior to FDA approval. Of the systems with biphasic waveforms, 19 were implanted with unapproved combinations of approved pulse generators

and leads ("off-label"), and 89 were implanted prior to FDA approval of the lead or pulse generator or both. Patients who underwent implantation of an unapproved lead system or pulse generator gave informed consent under an investigational protocol approved by the Institutional Review Board of Eastern Virginia Medical School.

Patient Characteristics

Characteristics of the 245 patients who received transvenous ICDs are summarized in Table 2. Of the 129 patients who received monophasic devices, 18 had no inducible ventricular arrhythmias during the initial electrophysiologic study. The remaining 111 patients failed to respond to 1.6 ± 1.0 (mean \pm SD) drug trials prior to implantation. Of the 116 patients who received biphasic devices, 10 had no inducible ventricular arrhythmias during the baseline electrophysiologic study. The remaining patients failed to respond to a mean of 0.69 ± 0.89 drugs prior to implantation. Serial drug testing was performed significantly more frequently before implantation of monophasic devices ($P=0.0001$) than of biphasic devices. There were no significant differences between the two patient groups in terms of age, sex, ejection fraction, or underlying heart disease.

Implantation of Lead Systems

All patients receiving monophasic pulse generators received the CPI Endotak lead system (models 0060, 0062, 0064, 0070, 0072, and 0074). Lead systems used in the patients receiving biphasic pulse generators included the CPI Endotak, Medtronic Transvene, and Ventritex TVL (Tables 1 and 2). All devices and lead systems were implanted in the operating room or electrophysiology laboratory with patients under general endotracheal anesthesia.

In most patients, venous access for the transvenous defibrillation lead was provided through the left subclavian vein, unless a previously implanted pacing system or other factor mandated placement via the right subclavian vein. The distal defibrillating electrode was positioned in the right ventricular apex, with the proximal defibrillating electrode positioned in the right atrium or superior vena cava. Pacing and sensing thresholds were con-

Table 1. Implantable Cardioverter Defibrillator Systems

Pulse Generator		Lead System		N
Manufacturer	Model	Manufacturer	Model	
Monophasic Waveforms				
CPI	1550/1555/1600	CPI	Endotak	81
CPI	1700/1705	CPI	Endotak	48
Biphasic Waveforms				
CPI	1625/1715	CPI	Endotak	22
Ventritex	V100/V110	CPI	Endotak	64
Ventritex	V100/V110	Ventritex	TVL	15
Medtronic	7219	Medtronic	Transvene	15

CPI = Cardiac Pacemakers, Inc.

firmed. Conversion of ventricular fibrillation was first tested using the transvenous lead or leads alone. Ten patients with defibrillation thresholds greater than 25 joules with transvenous lead(s) alone required implantation of a subcutaneous patch or array electrode. Intraoperative defibrillation testing was performed to confirm consistent defibrillation thresholds of 20 joules or less.

Analysis of Direct Costs

All direct hospital costs incurred during the hospitalization in which defibrillator implantation occurred were analyzed. Direct costs included dollars paid for supplies; personnel costs, including salaries and benefits; and depreciation on capital equipment. Itemized patient bills, obtained from the inpatient billing office, were used to analyze direct costs beginning on the day of implantation. Bills were sorted and organized by date and cost center and were inspected for any late charges related to implant care. Costs of subsequent hospitalizations for system revision were analyzed separately. Pulse generator and lead costs were analyzed separately as hardware costs. Costs of pulse generator replacement at anticipated end of life were excluded. Hospital costs included room and board, electrophysiology and operating room costs, nursing and ancillary care, blood tests, radiographs, electrocardiograms, cardiac imaging studies, and pharmacy costs. Cost of the pre-discharge testing of the defibrillator in the electrophysiology laboratory also were included.

Several methods were used to analyze direct costs. Costs for procedures and nursing care included costs of salaries plus benefits, costs for disposable equipment, and depreciation on capital equipment. Additional data were obtained from the materials management department at Sentara Norfolk General Hospital and from a commercially available inventory

system (Enterprise Systems, Inc). These three methods were applicable to 95% of the cost entries.

For the remaining 5% of entries, less-direct methods, including the Medicare ratio of cost to charges, were used. Finally, in the absence of accurate data, a gross margin of 70% on hospital charges was assumed.

Statistical Analysis

Data are reported as means plus or minus the standard deviation. Continuous variables were compared using Student's t-test. Survival analyses were performed using Kaplan-Meier statistics. A P value of less than 0.05 was considered statistically significant.

... RESULTS ...

All patients were monitored for at least 24 hours postoperatively and underwent pre-discharge defibrillation threshold testing. Patients were followed postoperatively in the Pacemaker Center at Sentara Norfolk General Hospital. After discharge, complications and system malfunctions requiring revision were analyzed. The direct costs of procedures related to device malfunction and complications associated with device and lead implantation were analyzed using an intention-to-treat analysis.

Monophasic Group

In the monophasic group, 62 procedures were performed in 57 patients because of complications with devices or lead systems. Of the 14 patients with monophasic devices who experienced failure to convert VT or ventricular fibrillation at pre-discharge testing, 6 required subcutaneous patch placement, 6 underwent transvenous lead repositioning or addition of a new transvenous lead, 1 had a model 1550 explanted and a model 1555 implanted, and 1 had a subcutaneous array added. At the 1- to 3-month electrophysiologic

Table 2. Patient Characteristics

	Monophasic Waveforms		Biphasic Waveforms			
	CPI 1500/1555/1600 Endotak	CPI 1700/1705 Endotak	CPI 1625/1715 Endotak	Ventritex V100/V110 Endotak	Ventritex V100/V110 TVL	Medtronic 7219 Transvene
Number of Patients	81	48	22	64	15	15
Male (%)	63	40	17	46	13	10
EF% (mean ± SD)	33.9 ± 13.0	36.9 ± 15.0	42.5 ± 18.6	30.8 ± 13.7	35.7 ± 15.1	33.3 ± 15.4
Age (year; range)	23 - 84	28 - 85	40 - 77	22 - 80	44 - 76	16 - 78
CAD (%)	67.9	60.4	41.0	60.9	81.0	62.4

study, 16 patients failed to convert VT or ventricular fibrillation satisfactorily. Of the 16, 12 underwent lead repositioning, 3 underwent placement of transvenous sensing leads, and 1 underwent a subcutaneous array addition.

Premature end of life of monophasic devices occurred in 6 patients. There were nine device infections in this group, and 5 patients underwent reimplantation. Late sensing lead fractures occurred in 12 patients; all 12 received new transvenous sensing leads. Two patients received biphasic pulse generators because the original monophasic pulse generators failed to convert spontaneous VT satisfactorily.

Biphasic Group

Nine complications required revisions in the biphasic group. Complications included random component failure in two patients and infections in two patients who underwent system replacement.

Five patients required patch placement and/or lead reposition, due to the inability to convert ventricular fibrillation satisfactorily at the predischarge study.

Costs of Pulse Generators

Pulse generator costs for monophasic and biphasic devices were similar (Table 3). Because of the improved defibrillation thresholds associated with the biphasic pulse generators, the addition of a subcutaneous patch or array was required less frequently with these devices, reducing lead system costs. Device and lead costs for CPI models 1550, 1555, and 1600 were $\$22,375 \pm \$1,391$. For the CPI models 1700 and 1705, costs were $\$24,952 \pm \692 . Device and lead costs for the CPI models 1625 and 1715 were $\$24,809 \pm \908 . The costs for the Ventritex models V100 and V110 with a CPI Endotak lead system were $\$24,706 \pm \$1,327$. The costs for the Ventritex TVL lead system were $\$19,738 \pm \$1,160$. The Medtronic model 7219 with the Transvene lead system cost $\$25,200 \pm \495 . There were no statistically significant differences in costs among the pulse generators and lead systems.

Table 3. ICD System Hardware Costs

Pulse Generator		Lead System		Costs (Mean \pm SD)
Manufacturer	Model	Manufacturer	Model	
Monophasic				
CPI	1550/1555/1600	CPI	Endotak	$\$22,375 \pm 1,391$
CPI	1700/1705	CPI	Endotak	$\$24,952 \pm 692$
Biphasic				
CPI	1625/1715	CPI	Endotak	$\$24,809 \pm 908$
Ventritex	V100/V110	CPI	Endotak	$\$24,706 \pm 1,327$
Ventritex	V100/V110	Ventritex	TVL	$\$19,738 \pm 1,160$
Medtronic	7219	Medtronic	Transvene	$\$25,200 \pm 495$

Hospital Costs

Direct hospital costs were analyzed from the date of implant to the date of discharge (Table 4). This analysis included all costs related to device implantation, recovery, and predischarge testing. All costs, including those associated with management of high defibrillation thresholds at the time of implantation and failure to defibrillate at predischarge testing, were included.

In the monophasic group, hospital costs for CPI models 1550, 1555, and 1600 were $\$8,404 \pm \5062 . For CPI models 1700 and 1705, hospital costs were $\$7,838 \pm \$4,866$. In the biphasic group, hospital costs for CPI models 1625 and 1715 were $\$3,354 \pm \$1,025$; for the Ventritex

Table 4. Hospital Costs from Implant Date to Discharge Date

Pulse Generator		Lead System		Costs (Mean \pm SD)
Manufacturer	Model	Manufacturer	Model	
Monophasic				
CPI	1550/1555/1600	CPI	Endotak	$\$8,404 \pm 5,062$
CPI	1700/1705	CPI	Endotak	$\$7,838 \pm 4,866$
Biphasic				
CPI	1625/1715	CPI	Endotak	$\$3,354 \pm 1,025$
Ventritex	V100/V110	CPI	Endotak	$\$3,741 \pm 2,135$
Ventritex	V100/V110	Ventritex	TVL	$\$4,898 \pm 2,614$
Medtronic	7219	Medtronic	Transvene	$\$2,690 \pm 790$

V100 and V110 Endotak group were \$3,741 ± \$2,135, and for the Ventritex TVL group, \$4,898 ± \$2,614. In the Medtronic 7219/Transvene group, hospital costs were \$2,690 ± \$790. Hospital costs were lowest with the Medtronic model 7219 because the majority of device implants were performed in the electrophysiology laboratory, rather than in the operating room.

Length of Initial Hospitalization

Length of stay from implant to discharge was 5.6 ± 4.7 days for patients in the monophasic group. In the biphasic group, the average length of stay from implant to discharge was 5.0 ± 5.2 days in patients undergoing implantation in the operating room (*P* = NS) and 2.6 ± 1.3 days (*P* = 0.01 compared with all devices implanted in the operating room) in patients undergoing implantation in the electrophysiology laboratory.

Costs for Revision

The direct cost for management of complications requiring revision (*n* = 57) was \$6,925 ± 4,837 in the monophasic group. For patients with biphasic devices, the direct cost of complications requiring revision (*n* = 8) was \$6,103 ± 3,473 (*P* = NS).

Total Costs of ICD Therapy

At 30 months after implantation, the mean total cost of initial implantation and complications was \$11,948 for each device in the monophasic group. In the biphasic group, this cost was \$8,290 for each device (Figure 1).

Survival

Survival for all-cause mortality at 30 months was 79.0 ± 5.0% in the monophasic group and 83.3 ± 5.9% in the biphasic group (Figure 2). Survival for sudden cardiac death at 30 months was 97.6 ± 1.7% in the monophasic group and 92.0 ± 4.8% in the biphasic group (Figure 3).

... DISCUSSION ...

ICDs have become a standard therapy for sudden cardiac death and recurrent sustained VT.¹¹ In recent years, ICD technology has advanced rapidly and implantation rates have increased dramatically. As technology has advanced, implantation costs have decreased. Two major advances have occurred in the implantation technique—the introduction of the transvenous lead system and pectoral implantation in the electrophysiology laboratory. Each of these advances has been associated with lower hospital costs.

We have shown that long-term costs associated with pulse generators with biphasic waveforms are lower than those with monophasic waveforms, particularly when used with transvenous leads. These systems have lower and more stable defibrillation thresholds and require fewer late revisions. Thus, despite the substantial cost discounts now being offered on older devices, the newer devices may be associated with lower long-term costs.

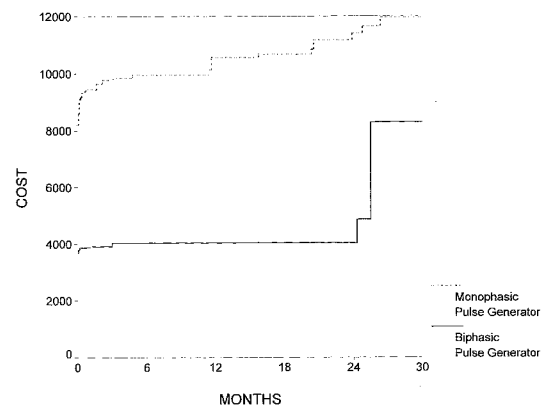


Figure 1. Cost analysis of monophasic and biphasic pulse generators. The x-axis shows the number of months post-pulse-generator implantation. The y-axis shows hospital costs. The y-intercepts represent the average hospital costs of the initial pulse generator implantations. The curves represent the increase in average cost over time, as revisions are required while the number of pulse generators in the groups decline. Monophasic pulse generators cost an average of \$11,948 by 30 months postimplantation. Biphasic pulse generators cost an average of \$8,290 by 30 months postimplantation (*P* = 0.02).

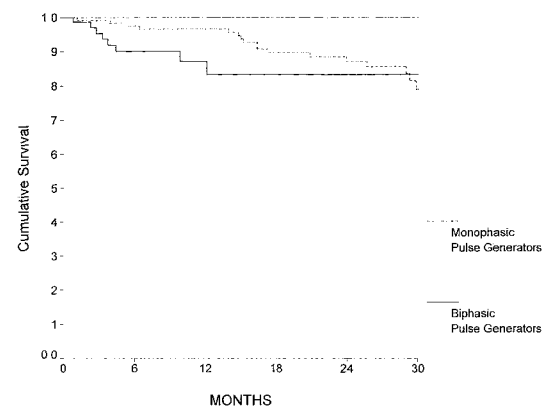


Figure 2. Survival for all-cause mortality in patients with monophasic and biphasic pulse generators. Survival curves were generated using Kaplan-Meier survival analysis. The x-axis shows the number of months post-pulse-generator implantation. The y-axis shows the percentage of patients surviving. In the monophasic pulse generator group, 79.0% remained alive at 30 months. In the biphasic pulse generator group, 83.3% remained alive at 30 months.

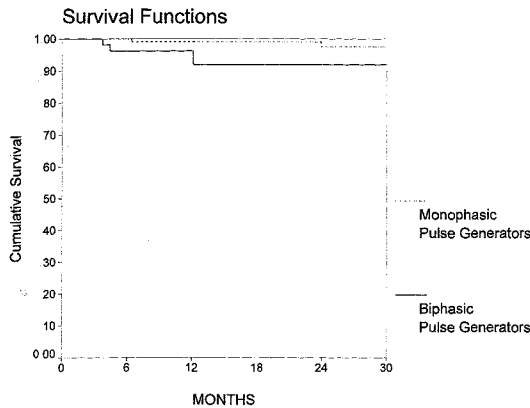


Figure 3. Survival for sudden cardiac death in patients with monophasic and biphasic pulse generators. Survival curves were generated using Kaplan-Meier survival analysis. The x-axis shows the number of months post pulse generator implantation. The y-axis shows the percentage of patients surviving. In the monophasic pulse generator group, 97.6% remained alive at 30 months. In the biphasic pulse generator group, 92.0% remained alive at 30 months.

Most of the systems evaluated in this study were implanted on an investigational basis. At each stage of technological development, only investigational devices provided the latest and ultimately most cost-effective technology.

Years of investigation and development preceded each element of transition, from implantation requiring a thoracotomy in the operating room with monophasic devices, to transvenous implantation in the operating room with monophasic devices, to transvenous implantation in the operating room with biphasic devices, and, most recently, to transvenous implantation in the electrophysiology laboratory with biphasic devices. Retrospectively, each of these elements has decreased costs of ICD therapy. Recent clarification of HCFA rules and regulations forbids payment for care surrounding investigational device implantation. In addition, many commercial third-party payers are denying reimbursement for investigational devices. Not only do these policies slow development of cost-saving technology, but they also

perpetuate higher costs during the period when lower-cost technologies could be made available on an investigational basis.

In summary, although the initial costs of monophasic devices may be lower than those of biphasic devices, long-term costs associated with these devices are higher. Immediate and long-term costs of ICD care would be lower if HCFA and third-party payers allowed the use of investigational devices. Emerging technology should be used when cost savings can be realized.

Acknowledgment

The authors gratefully acknowledge the assistance of Mr. Jeffrey Hartman for assessment of actual hospital costs.

... REFERENCES ...

1. Kelly PA, Cannon DS, Garen H, et al. The automatic implantable defibrillator (AICD): Efficacy, complications and survival in patients with malignant ventricular arrhythmias. *J Am Coll Cardiol* 1988;11:1278-1286.
2. Meyerburg RJ, Castellanos A. Evolution, evaluation and efficacy of implantable cardioverter defibrillators technology. *Circulation* 1992;86:691-693
3. Food and Drug Administration. *Federal Register* 1985; 50:47276.
4. Saksena S. The impact of implantable cardioverter defibrillator therapy on health care systems. *Am Heart J* 1994;127:1193-1200.
5. Cuppermann M, Luce BR, McGovern B, et al. An analysis of the cost effectiveness of the implantable defibrillator. *Circulation* 1990;81:91-100.
6. Leaf A. Cost effectiveness as a criterion for Medicare coverage. *N Engl J Med* 1989;321:898-900.
7. Williamson BD, Man KC, Niebauer M, et al. The economic impact of transvenous defibrillation lead systems. *Pacing Clin Electrophysiol* 1994;17:2297-2304.
8. Saksena S, An H, Mehra R, et al. Prospective comparison of biphasic and monophasic shocks for implantable cardioverter-defibrillators using endocardial leads. *Am J Cardiol* 1992;70:304-310.
9. Eisenberg JM. Clinical economics: A guide to the economic analysis of clinical practices. *JAMA* 1989;262:2879-2886.
10. Detsky AS, Naglie IG. A clinician's guide to cost-effectiveness analysis. *Ann Intern Med* 1990;113:147-154.
11. de Lissovoy G, Guarnieri T. Cost-effectiveness of the implantable defibrillator. *Prog Cardiovasc Dis* 1993;36: 209-213