The Economic Impact of Transvenous Defibrillation Lead Systems

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WILLIAMSON, B.D., ET AL.: The Economic Impact of Transvenous Defibrillation Lead Systems. *The purpose of this study was to compare implant charges and convalescence for transvenous and epicardial defibrillation systems. Hospital stay, intensive care utilization, professional fees, and hospital bills were compared in 44 patients who underwent implantation of a cardiac defibrillator between September 1991 and May 1993. Twenty-five consecutive patients received an epicardial lead system, while 19 consecutive patients underwent implantation of the entire transvenous defibrillation system in the electrophysiology laboratory. There were no significant differences between the two groups in mean age or left ventricular ejection fraction. There was a significant reduction in postoperative hospital convalescence from 7.2 ± 2.0 days with epicardial systems to 3.1 ± 1.5 days with transvenous systems ($P < 0.001$). Postoperative intensive care unit stay was significantly reduced with transvenous systems compared with epicardial systems (0.1 ± 0.2 vs 1.5 ± 0.9 days; $P < 0.001$). Hospital charges were also significantly reduced with the transvenous lead system implants. Mean implant charges were lower with transvenous systems: $32,090 ± $2,620 vs $38,307 ± $2,701 ($P < 0.001$); convalescence charges were lower: $5,861 ± $5,010 vs $12,447 ± $4,969 ($P < 0.001$); the total hospital bill was also significantly lower with transvenous systems: $53,459 ± $12,588 vs $71,981 ± $16,172 ($P < 0.001$). Professional fees for implantation ($4,131 ± $1,724 vs $6,100 ± 0, $P < 0.001$), convalescence care ($1,258 ± $960 vs $2,846 ± $1,770; $P < 0.001$), and total professional fees ($12,925 ± $4,772 vs $15,731 ± $4,055, $P < 0.05$) were lower in the transvenous defibrillation group. In conclusion, transvenous defibrillation lead systems are associated with significantly shorter postoperative recovery and significantly lower hospital and professional charges. (PACE 1994; 17[Pt. I]:2297–2303)*

implantable cardiac defibrillation, transvenous defibrillation leads

Introduction

Cardiac defibrillators using epicardial defibrillation lead systems were approved for clinical use by the Food and Drug Administration on October 4, 1985.[1] Since that time, several studies have suggested that the implantable defibrillator prolongs survival in patients who are at risk of arrhythmic death.[2–5] With this sophisticated technology comes a substantial financial cost. Not only is the device expensive, but implantation of this defibrillation system requires entry into the thorax. The convalescence in these patients involves a stay in the intensive care unit, followed by several additional days in the hospital prior to discharge. Nevertheless, cost analysis studies have suggested that implantable defibrillators with epicardial defibrillation systems have a cost that compares favorably with that of other life-saving interventions.[6,7]

A transvenous defibrillation lead system was approved for clinical use by the Food and Drug Administration in August 1993.[8] Transvenous defibrillation lead systems eliminate the need for entry into the thorax, which may result in lower morbidity and mortality and a shorter hospitaliza-

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tion. The purpose of this study was to compare the total charges and duration of convalescence in patients undergoing implantation of transvenous and epicardial defibrillation lead systems.

Methods

Subjects of Study

All patients with aborted sudden cardiac death not due to correctable causes or with medically refractory ventricular tachycardia receiving a clinically available cardiac defibrillator at the University of Michigan between September 1991 and May 1993 were considered for evaluation. Patients requiring concomitant cardiac surgery were excluded. All patients underwent a baseline electrophysiological study in the absence of antiarrhythmic agents. If monomorphic ventricular tachycardia was induced with programmed stimulation during the baseline study, electropharmacological testing was performed. Patients who continued to have inducible ventricular tachycardia despite drug therapy or who did not have inducible ventricular tachycardia during the baseline study underwent cardiac defibrillator implantation. The epicardial group consisted of 25 patients who received an epicardial lead system before an investigational defibrillation lead system was available in our institution. Once investigational transvenous defibrillation lead systems became available, all patients undergoing cardiac defibrillator implantation without concomitant cardiac surgery were eligible for the transvenous defibrillation lead system. The transvenous defibrillation group consisted of 19 consecutive patients receiving an investigational transvenous defibrillation lead system made by Cardiac Pacemakers, Incorporated (CPI, St. Paul, MN, USA). All patients in this analysis received clinically available defibrillator generators. Patients who underwent implantation of a transvenous lead system provided informed consent under an investigational protocol approved by the Human Research Committee.

The total study group consisted of 44 patients receiving implantable cardiac defibrillators (Table I). Among the 25 patients who received a cardiac defibrillator with an epicardial defibrillation system, 16 were noninducible during the initial electrophysiological study. The remaining nine patients failed a mean of 1.8 drug trials prior to implantation. Among the 19 patients who received a cardiac defibrillator with a transvenous lead system, 10 patients were noninducible during the baseline electrophysiological study. The other nine patients failed a mean of two drug trials prior to implantation. There were no significant differences between the two groups in age, ejection fraction, New York Heart Association class, or prior antiarrhythmic therapy.

Table I.
Clinical Features of Study Groups

	Epicardial Group	Transvenous Group
Number	25	19
Age (years)	64 ± 9	60 ± 12
Ejection fraction	0.33 ± 0.13	0.34 ± 0.17
Prior amiodarone therapy	9/25	9/19
Males/Females	20/5	19/1
NYHA Class CHF:		
I	5	6
II	15	11
III	5	2

There were no significant differences between the two groups.

Implantation of Epicardial Lead Systems

In the epicardial group, the surgical approach for implantation of epicardial lead systems was median sternotomy or left anterior thoracotomy. Implantation was performed in the operating room with the patient under general anesthesia. Two large patch leads were used in the majority of patients, and two epicardial rate sensing leads were placed in all epicardial systems. Intraoperative defibrillation was performed to confirm consistent defibrillation with 20 joules or less. Postoperatively, all patients undergoing thoracotomy were monitored for at least 24 hours in an intensive care unit. Patients were moved to a monitored intermediate care unit once they were stable.

Implantation of Transvenous Lead Systems

In the transvenous group, the entire implantation procedure was performed in the electrophysiology laboratory with the patient under general an-

esthesia. Venous access for the transvenous defibrillation lead in most patients was through the left subclavian vein, unless existing pacemaker hardware or other surgical factors required entry by the right subclavian vein. The defibrillator lead was positioned in the right ventricular apex to achieve satisfactory bipolar sensing and pacing. Conversion of ventricular fibrillation was first tested using a lead alone. Nine patients with defibrillation thresholds higher than 25 joules with transvenous lead alone underwent implantation of a subcutaneous subaxillary patch electrode.

All patients went to a postoperative observation area after the completion of the transvenous implant procedure. They remained there until the anesthesiologist judged them stable to return to their room in an intermediate care monitored unit. One of 19 patients receiving a transvenous defibrillation system was monitored overnight in an intensive care unit. All patients underwent a predischarge test of the cardiac defibrillator.

Postoperative Recovery

All patients had satisfactory defibrillation at initial implant. One patient in the epicardial lead system group had unsatisfactory defibrillation at the predischarge test, and underwent additional implantation of a spring lead in the superior vena cava-right atrium to achieve satisfactory defibrillation. One patient in each group underwent implantation of a dual chamber pacemaker prior to discharge from the hospital. One patient in the epicardial group developed postoperative atrial fibrillation with a rapid ventricular response, resulting in several defibrillator discharges; another patient in this group developed a sterile fluid collection around the defibrillator generator. One patient in the transvenous group had inadvertent entry into the abdominal cavity through a preexisting ventral hernia when the generator pocket was formed, without clinical sequelae. Another patient in the transvenous group had mild postoperative corneal abrasions of one eye, which resolved with conservative therapy. There were no deaths or serious complications from defibrillator implantation in either group.

Analysis of Charges and Convalescence

All hospital charges during the hospitalization in which the defibrillator implant occurred were analyzed. Itemized bills were obtained from the patient accounts office. The hospital charges included charges for room and board, electrophysiology, and operating room charges, nursing and ancillary care, blood tests, chest roentgenograms, electrocardiograms, cardiac imaging studies, and pharmacy charges. Implant-related charges were defined as all hospital charges generated on the day of implantation, including direct operating room and supply charges, device charges, radiology and laboratory fees, patient room and recovery room charges where applicable. Convalescence charges included all charges incurred from the day after implantation until discharge, including patient room, pharmacy, laboratory, and radiology charges. All patients underwent a predischarge test of the cardiac defibrillator in the electrophysiology laboratory, the fee for which was included in convalescence charges.

Physician charges were obtained from the relevant physician associates group at the University of Michigan (i.e., Internal Medicine, Thoracic Surgery, and Anesthesiology). To account for any changes in charges due to inflation, cost data in this study were adjusted to 1993 dollars. Hospital and physician charges were adjusted using an average annual inflation rate obtained from the University of Michigan Medical Center budget and medical service plan offices, respectively.

Return to Work

Follow-up telephone interviews were conducted to assess postimplantation employment status. Interviews included demographics, such as marital status, number of children, and years of formal education. Full- or part-time employment status as well as occupational level (unskilled, skilled, technical, and professional) were also assessed. Finally the level of reemployment and days until return to work were obtained.

Statistical Analysis

Data are reported as mean ± standard deviation. Continuous variables were compared with Student's *t*- test. Discrete variables were compared by contingency table analysis. A P value < 0.05 was considered statistically significant.

Results

Total Charges

Patients receiving an implantable cardiac defibrillator with an epicardial defibrillation lead system incurred an average of $87,318 ± $14,046 in total charges, including both total hospital charges and professional fees. In contrast, patients who received an implantable cardiac defibrillator utilizing a transvenous defibrillation lead system had a significantly lower mean total charge of $66,627 ± $18,867 ($P < 0.001$).

Professional Fees

The professional fees were similar in the two groups for the preimplantation period of the hospitalization (Table II), with mean professional fees in the epicardial group of $6,192 ± $3,631, and $6,390 ± $4,266 in the transvenous group (P = NS). These fees represent the total professional fees during the evaluation phase prior to implantation, including electrophysiological studies, cardiac catheterizations, electrocardiograms, echocardiogram and nuclear study interpretation, as well as patient care days.

The implantation professional fees were those fees incurred on the day of defibrillator implantation. Epicardial lead system implantations resulted in professional fees of $6,100 ± 0, whereas transvenous lead system implants resulted in professional fees of $4,131 ± $1,724, which were significantly lower ($P < 0.001$). The difference in the observed fees was due to the involvement of only one physician group (electrophysiologist) performing the transvenous lead system implantation compared to a cardiothoracic surgeon and electrophysiologist in the epicardial lead system implantations.

The professional fees during the convalescence period were significantly lower for patients with transvenous lead systems. The fees incurred for convalescence care included not only a predischarge test of the cardiac defibrillator, but also interpretations of electrocardiograms, arterial blood gases, echocardiograms (if performed), and any medical consultations. Patients receiving an epicardial lead system incurred $2,846 ± $1,770 of professional charges during the convalescence period, compared with $1,258 ± $960 for patients with transvenous lead systems, a difference that was statistically significant ($P < 0.001$). This overall reduction in professional service utilization was also reflected in significantly lower total professional fees in the transvenous lead system group ($12,925 ± $4,772 vs $15,731 ± $4,055 in the epicardial group, $P < 0.05$).

Hospital Charges

There were significantly lower hospital charges for patients receiving a transvenous cardiac defibrillation system compared with patients receiving epicardial lead systems (Table III). Implant-related charges, reflecting all hospital charges incurred on the day of implantation, were lower in the transvenous group: $38,307 ± $2,701 versus $32,090 ± $2,620 in the epicardial group ($P < 0.001$). There was also a significant reduction in hospital charges incurred during the subsequent hospital convalescence. The epicardial group incurred $12,447 ± $4,969 in charges during the mean of 7.2 days of convalescence; the transvenous group incurred $5,861 ± $5,010 in charges

Table II.

Professional Fees

	Epicardial Group	Transvenous Group	P
Preimplant	$6,192 ± 3,631	$6,390 ± 4,266	NS
Implant	$6,100 ± 0	$4,131 ± 1,724	< 0.001
Convalescence	$2,846 ± 1,770	$1,258 ± 960	< 0.001
Total	$15,731 ± 4,055	$12,925 ± 4,772	< 0.05

Comparison of total professional fees for epicardial and transvenous defibrillation lead systems, respectively.

Table III.
Convalescence and Hospital Charges

	Epicardial Group	Transvenous Group	P
Convalescence (days)	7.2 ± 2.0	3.1 ± 1.5	< 0.001
ICU convalescence (days)	1.5 ± 0.9	0.1 ± 0.2	< 0.001
Total hospital stay (days)	18.7 ± 6.1	14.2 ± 6.2	< 0.01
Implant charges ($)	$38,307 ± 2,701	$32,090 ± 2,620	< 0.001
Convalescence charges ($)	$12,447 ± 4,969	$5,861 ± 5,010	< 0.001
Total Hospital Charges	$71,981 ± 16,172	$53,459 ± 12,588	< 0.001

during 3.1 days of convalescence, a 55% reduction in convalescence charges, which was statistically significant ($P < 0.001$).

Length of Hospitalization and Convalescence

Patients in the epicardial group had an average total length of stay of 18.7 ± 6.1 days, with 7.2 ± 2.0 days spent as in-hospital convalescence after defibrillator implantation (Table III). The average intensive care unit convalescence in the epicardial group was 1.5 ± 0.9 days. One patient remained in the intensive care unit for 3 days, and another for 5 days after surgery. In comparison, patients receiving a transvenous cardiac defibrillation lead system had a significantly shorter hospital stay, 14.2 ± 6.2 days ($P < 0.01$). This difference was due to a shorter total postimplant convalescence time of 3.1 ± 1.5 hospital days ($P < 0.001$). The patients in the transvenous group also required significantly less intensive care convalescence following implant, 0.1 ± 0.2 days, with only one patient spending 1 day in the intensive care unit ($P < 0.001$).

Return to Work

Five patients in the epicardial group were employed prior to implantation of the defibrillator, and three have returned to work during the follow-up period (Table IV). The mean time for returning to work was 104 days, (range 42–180 days). Seven patients in the transvenous group were employed prior to implantation, and three returned to work afterwards, with a mean time to return of 66 days (range 7–150 days). No patient in either group who was not employed prior to implantation began to work after implantation.

Discussion

Main Findings

The care of patients with aborted sudden death or ventricular tachycardia is expensive because of the required diagnostic evaluation, hospitalization, and therapy. If the decision is made to implant a cardiac defibrillator, considerable expense is incurred from the operative implant, the cost of the device, and the subsequent postimplant convalescence. The results of this study demonstrate an overall savings of 23% in hospital charges and professional fees in patients receiving an implantable cardiac defibrillator utilizing a transvenous lead system compared to an epicardial defibrillation system. Transvenous defibrillation lead systems offer a significant reduction in consumption of expensive hospital resources compared with epicardial lead systems.

Table IV.
Return to Work

	Epicardial Group	Transvenous Group
Preimplant Employment	5 (20%)	7 (37%)
Full-time	4	4
Part-time	1	3
Return to work	3 (13%)	3 (16%)
Days to return to work*	104 ± SD	66 ± SD
Range (days)	42–180	7–150

* Average days until return to previous level of employment. Difference not statistically significant.

Professional Fees

The professional component of patient charges was 17% lower in patients receiving a transvenous lead system compared with epicardial systems. There was no difference in professional fees for the preimplantation period of the hospitalization. This confirms the similarity in patient complexity in the two groups prior to implantation. Implantation professional fees were significantly lower, resulting in a 32% savings for the professional component of implant charges. This reduction in incurred charges resulted from the ability of the transvenous system to be implanted by an electrophysiologist without the involvement of a cardiothoracic surgeon. Professional charges in the transvenous group were 63% lower during the convalescence period, reflecting the shorter postoperative hospitalization and lower complexity of postoperative care in these patients.

Hospital Charges

This study examined the impact of transvenous defibrillation lead systems on hospital charges as a measure of their impact on cost effectiveness. Hospital charges are not the same as "cost," nor do hospital charges reflect reimbursement from third-party payers. However, it is generally acknowledged that hospital charges are proportional to the consumption of resources. Reductions in accrued charges for similar services should reflect a legitimate reduction in resource consumption. In this study, not only were charges reduced, but the transvenous defibrillation lead system also resulted in a significant reduction in length of stay and intensity of care.

Return to Work

As a previous study of return to employment in patients receiving epicardial defibrillation systems found, the employment status prior to defibrillator implantation has a strong influence on subsequent employment.[9] The number of patients in this study who were employed prior to implantation of their cardiac defibrillator was low. No patients who were on medical disability or who were retired prior to implantation became employed after implant. Although the number of patients who returned to work in each group was small, there was a trend toward earlier return to work in patients who received a transvenous defibrillation system.

Comparison with Other Studies

The patients receiving epicardial defibrillation systems in this study had hospital costs and length of stay similar to a recently published analysis of the cost effectiveness of automatic defibrillator implantation.[7] In that study, patients who failed drug therapy underwent left anterior thoracotomy or subxiphoid implantation of the defibrillation system, with a subsequent average hospital stay of 26.3 days and an average cost of $73,400. Furthermore, early implantation of a cardioverter-defibrillator without drug testing resulted in an average length of stay of 12.6 days and an average cost of $40,400, both of which were significantly lower than in patients who first underwent drug testing. Given the findings in the current study, early implantation of a transvenous cardiac defibrillator may be the most cost-efficient way to treat patients who have had a life-threatening arrhythmia. Future efficacy studies comparing early implantation of a transvenous defibrillator system with long-term drug therapy will be necessary to further investigate this possibility.

No previous study has addressed the impact of transvenous defibrillator systems on out-of-hospital convalescence or returning to work. A shorter time for return to previous activities after transvenous defibrillator implantation could offer a significant financial benefit to those patients who do return to work. Although many patients may not be employed due to advanced age, poor cardiac function, or other medical problems, shorter post-discharge convalescence also allows for improved quality of life.

Limitations

This study focused on differences in the immediate postoperative convalescence and on the impact of defibrillation lead systems on the cost of the initial hospitalization, but did not examine the cost of care during long-term follow-up. During the initial investigational phase, a 2-month electrophysiological study to reevaluate efficacy of defibrillation was required in the transvenous group, but not in the epicardial system group. However,

because the Endotak lead system has been clinically released by the Food and Drug Administration, the need for a 2-month follow-up study is now at the discretion of the following physician. In the manufacturer-reported experience in 1,432 patients with the Endotak lead, 1.4% of patients were found to have nonconversion of arrhythmia 8–12 weeks postimplant, and 0.3% were found to have nondetection of arrhythmia.[8] As with the epicardial lead systems, follow-up testing should be performed when clinically indicated. Since the defibrillator generator is the same for both defibrillation lead systems, the clinical follow-up is otherwise the same.

Although all patients in this study had successful defibrillation with the transvenous lead system, some patients may not achieve satisfactory defibrillation without epicardial patches. In the initially reported manufacturer experience, 1,432 of 1,652 (86%) of patients underwent successful implantation of a transvenous system. In the latter part of the study, the implant success rate was 91.2% (611 of 670 patients). In the limited number of patients who require epicardial patches after attempted transvenous implantation, the cost of care increases. Future advances in defibrillation technology, including biphasic waveforms, may further improve the efficacy of transvenous defibrillation. Additionally, technological advances in defibrillation efficacy and reduction in generator size may allow for prepectoral implantation, which might eliminate the need for general anesthesia and its associated cost.

Although the patients in this study were not randomly assigned to the type of defibrillator system that was implanted, the two groups of patients were demographically similar and underwent implantation of their devices within a relatively short time interval. Therefore, differences in the patient groups or changes in clinical practice other than those changes related directly to the use of a transvenous instead of an epicardial system are unlikely to have influenced the results of this study.

Conclusion

Implantation of transvenous defibrillation lead systems is associated with significantly shorter postoperative recovery and significantly lower hospital and professional fees. Given the findings of this study, early implantation of a transvenous cardiac defibrillator may be more cost effective than pharmacological therapy in patients with life-threatening arrhythmias.

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