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Safety and Potential Cost Savings of Same-Setting Electrophysiologic Testing and Placement of Transvenous Implantable Cardioverter-Defibrillators

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Summary

Background: Separately, electrophysiologic study (EPS) and placement of a transvenous implantable cardioverter-defibrillator (ICD) can be performed safely in the majority of patients. The safety and potential cost savings of same-setting procedures have not been evaluated.

Hypothesis: Electrophysiologic study and placement of transvenous ICDs can be performed safely in the same setting at reduced cost.

Methods: In all, 160 (mean age 65 ± 10 years, 75% men) and 41 (mean age 66 ± 11 years, 73% men) consecutive patients who underwent same- versus separate-setting procedures, respectively, were prospectively evaluated.

Results: The two groups had similar clinical characteristics and indications for EPS and ICD therapy. Complications occurred in eight patients (5.0%, 95% confidence interval [CI] 2.3–10.3) who had same-setting procedures (one hypotension during ICD testing, one pocket hematoma, two lead dislodgments, two pneumothoraces, one stroke, and one infection) and in two (4.9%, CI 0.60–16.5) who had separate-setting procedures (one pocket hematoma and one infection). There were no procedure-related deaths or long-term ICD-related complications in either group. The mean time from ICD implantation to hospital discharge was similar in the two groups (2.5 ± 2.4 vs. 2.7 ± 2.2 days, p = NS). The combined procedure cost was higher in patients who had separate-setting procedures ($12,403 ± 1,386 vs. $10,242 ± 2,256, p = < 0.001), who incurred an additional hospital cost of $2,121 ± $2,125 for the waiting period (1.7 ± 1.6 days) between EPS and ICD implantation.

Conclusions: In patients deemed candidates for ICD therapy based on EPS results, placement of transvenous defibrillators in the same setting as EPS is as safe as separate-setting procedures and, if adopted, could further reduce the cost of providing ICD therapy.

Key words: cost, electrophysiologic study, implantable cardioverter-defibrillator

Introduction

In the past few years, the treatment of ventricular tachyarrhythmias has evolved from mainly antiarrhythmic drugs—often guided by electrophysiologic study (EPS)—to implantable cardioverter-defibrillator (ICD).[1] During the same period, ICD therapy has been shown to be superior to drug therapy in reducing total mortality in patients who have suffered[2] or are at risk of developing[3,4] life-threatening ventricular arrhythmias. In the majority of patients, improved technologies have facilitated successful implantation of purely transvenous ICD systems by electrophysiologists in the electrophysiology laboratory.[5–12] Although some patients with ventricular arrhythmias can be managed with ICDs without baseline EPS,[1,13] the need for device therapy is still based largely on the results of EPS; indeed, in some cases EPS plays a defining role.[3,4,14] Several factors have contributed to a lowering of the cost of ICD therapy.[15–19] In patients considered candidates for ICD therapy based on EPS results, same-setting device implantation might result in additional cost savings by reducing procedure cost and length of hospitalization, assuming the combined procedures do not result in increased complications. Performed separately, EPS[20] and insertion of transvenous ICDs[5–12] can be achieved with minimal risk in the majority of cases. Whether or not the same is true of combined procedures is unknown.

The purpose of this study was to evaluate prospectively the safety and potential cost savings of same-setting versus separate-setting EPS and implantation of transvenous ICDs in patients with ventricular arrhythmias who did not undergo initial antiarrhythmic drug therapy.

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Methods

Patient Population

Patients were included if they had baseline EPS and received ICDs in the electrophysiology laboratory without initial antiarrhythmic drug(s) testing. Patients who underwent ICD implantation without baseline EPS, after one or more antiarrhythmic drug trials, or in the operating room were excluded. Between July 1997 and April 2000, 160 consecutive patients received ICDs in the same setting following the completion of EPS, and 41 patients, who declined same-setting procedures, received ICDs at a later date as soon as they consented.

Electrophysiologic Study and Device Implantation

Both EPS and ICD implantation were performed according to accepted indications,[3, 14, 21, 22] and every patient gave written informed consent. Procedure details, including extensive teaching about ICD therapy and alternative forms of treatment, were provided to all patients and their family members. Programmed ventricular stimulation was performed as previously described.[3, 4] In patients with asymptomatic nonsustained ventricular tachycardia (VT), ICD therapy was generally decided based on response to intravenous (IV) procainamide.[3] In addition, in each case attention was paid to excluding specific mechanisms of VT (e.g., bundle-branch reentry) amenable to ablative therapy.[23] All devices were implanted pectorally as previously described.[8, 9] Successful implantation required that the tested lowest defibrillation energy be at least 10 J lower than the maximum output of the device. Procedure durations were calculated as follow: EPS—from placement of the femoral sheaths to their removal; ICD—starting with local anesthesia to closure of the incision; and total procedure—EPS and ICD procedures plus the elapsed time between completion of EPS and beginning of ICD implantation.

Postprocedure Care and Follow-Up

Patients were monitored in the recovery room or returned directly to their telemetry units depending on the level of sedation. Patients were discharged home within 24 to 48 h unless there were complications or they required non-ICD-related care. Reasons for delayed (after 48 h) hospital discharge and complications were tabulated. Every patient was seen in the office 1 to 2 weeks after hospital discharge and every 3 months thereafter. Predischarge ICD-testing was not routinely performed unless required by a study protocol, but testing was done 4 to 6 weeks after device implantation unless the patient had received ≥ 1 spontaneous ventricular fibrillation (VF) therapy.

Cost Analysis

Procedure costs, based on actual charges, included time spent in the electrophysiology laboratory, supplies (excluding cost of the device system, which varied over time) and anesthesia delivery; plus the cost ($1,210 per day) for any additional days of hospitalization spent between the time of EPS and ICD implantation. Laboratory charge was based on an initial flat rate of $1,100 plus additional charges for each 15-min period. Physician remuneration and patient-specific (e.g., medications) costs were not used in comparing cost. We did not compare the total length of hospitalization and cost since we could not control the timing of electrophysiology consultation and EPS (performed 4.2 ± 4.0 days after hospital admission) or non-EPS/ICD-related costs before and after the procedures.

Statistical Analysis

Continuous and categorical variables were compared, respectively, by Student's *t*-test and chi-square test. A p value of < 0.05 was considered statistically significant.

Results

The two groups had similar clinical characteristics and indications for EPS and ICD therapy (Table I). All patients who presented with nonsustained VT (n = 64) and syncope (n = 60) had left ventricular dysfunction with mean ejection fractions of 0.27 ± 0.10 and 0.27 ± 0.11, respectively. All but 16 patients (14 in the same-setting and 2 in the separate-setting) who presented with cardiac arrest had inducible unstable sustained VT (n = 164) or VF (n = 21); specific VT mechanisms (e.g., bundle-branch reentry) amenable to ablation therapy were not identified in any patient. Device implantation was achieved in all but one of the same-setting patients (lack of vascular access). All remaining 200 patients received hot can devices, with 48 patients in the same-setting and 6 in the separate-setting receiving dual-chamber ICDs. Both EPS (49 ± 22 vs. 52 ± 18 min, p = NS) and ICD (59 ± 18 vs. 55 ± 18 min, p = NS) procedure durations were similar in the two groups. The total same-setting procedure duration, including a 19 ± 6 min period between the completion of EPS and beginning of ICD implantation, was 114 ± 35 min. The mean intraoperative R wave amplitude (15 ± 4 vs. 13 ± 4 mV, p = NS) and lowest defibrillation energy (15 ± 5 vs. 14 ± 4 J, p = NS) were similar in patients who had same- versus separate-setting procedures, respectively.

Procedure-Related Complications

There were no complications attributable to EPS and no procedure or operative (30 days) deaths in either group. Procedure-related complications occurred in eight (5.0%, 95% confidence interval [CI] 2.3–10.3) and two (4.9%, CI 0.60–16.5) patients who had same- and separate-setting procedures, respectively (p = NS). In the same-setting group, hypotension occurred in one patient during ICD testing, requiring IV dopamine and overnight observation in the coronary care unit; one fully anticoagulated patient developed pocket hematoma requiring evacuation; two patients developed pneumothoraces; two patients with severe tricuspid regurgitation

TABLE I Patients' clinical characteristics

	Same-setting group (n = 160)	Separate-setting group (n = 41)	p Value
Age, years	65 ± 10	66 ± 11	
Men/women	120/40	30/11	NS
Heart disease			
Coronary artery disease (%)	131 (82)	34 (83)	
Nonischemic cardiomyopathy (%)	24 (15)	5 (12)	NS
Others (%)	5 (3)	2 (5)	
Prior coronary artery bypass surgery (%)	104 (65)	27 (66)	NS
Atrial fibrillation (%)	24 (15)	3 (7)	< 0.05
Left ventricular ejection fraction	0.27 ± 0.10	0.28 ± 0.10	NS
NYHA functional class	2.3 ± 0.56	2.2 ± 0.67	NS
Indications for electrophysiologic study			
Cardiac arrest	28 (17.5)	5 (12)	
Sustained VT	34 (21)	10 (25)	NS
Nonsustained VT [a]	52 (32.5)	12 (29)	
Syncope	46 (29)	14 (34)	

[a] and coronary artery disease with left ventricular ejection fraction ≤ 0.35.
Abbreviations: NYHA = New York Heart Association, VT = ventricular tachycardia, NS = not significant.

had lead dislodgment the day after surgery that was replaced with an active-fixation lead; and one patient developed a nonhemorrhagic (presumably embolic) stroke 6 h post procedure. One non-anticoagulated patient who had separate-setting procedures developed pocket hematoma requiring evacuation. One asplenic (same-setting) and one diabetic (separate-setting) patient developed ICD infection 6 and 8 weeks postoperatively, both requiring complete device removal. After a mean follow-up of 12 ± 6 and 19 ± 4 months for patients who had same- versus separate-setting procedures, respectively, no patient in either group had inappropriate therapy or required rehospitalization as a result of device-lead complications. Ten (6.2%) and four (10%) patients in the same- and separate-setting groups died of heart failure, and none suddenly.

Length of Hospitalization and Cost

The two groups were discharged at similar times after ICD implantation (2.6 ± 2.2 vs. 2.7 ± 2.2 days, p = NS). Overall, 145 of the 201 patients (72%) were discharged within 24 (n = 75) or 48 (n = 70) h (Table II). The reasons for delayed (> 48 h) hospital discharge for patients who had same- versus separate-setting procedures, respectively, included procedure-related complications (8 of 44 [18%] vs. 1 of 12 [8%]), exacerbation of VT/VF requiring antiarrhythmic drug treatment (4 of 44 [9%] vs. 2 of 12 [17%]), resumption of anticoagulation (20 of 44 [45%] vs. 5 of 12 [42%]) and non-ICD-related care (12 of 44 [27%] vs. 4 of 12 [33%]).

The combined EPS-ICD procedure cost was higher in patients who had separate-setting procedures ($12,403 ± 1,386 vs. $10,242 ± 2.256, p < 0.001), who incurred an additional cost of $2,121 ± 2,125 for the waiting period (1.7 ± 1.6 days) between the time of EPS and ICD implantation.

Discussion

This study shows that pectoral implantation of transvenous ICDs can be performed safely under conscious sedation in the same setting as EPS and at a cost lower than that for separate-setting procedures. The cost of providing ICD therapy, including the added waiting period between EPS and ICD implantation, was ≈ $4,300 (or ≈ 42%) higher in patients who had separate-setting procedures. Of those who underwent same-setting procedures, 72% were discharged within 48 h of ICD implantation.

The overall complication rates were similar in the two groups (~ 5%) and comparable with isolated ICD placements

TABLE II Reasons for delayed (> 48 h) hospital discharge in patients who had same- and separate-setting procedures [a]

	n (%)		
	Same-setting procedures	Separate-setting procedures	p Value
Device related			
Acute complications (%)	8/44 (18)	1/12 (8)	NS
Arrhythmia exacerbation (%)	4/44 (9)	2/12 (17)	NS
Non-device related			
Anticoagulation (%) [b]	20/44 (45)	5/12 (42)	NS
Others (%) [c]	12/44 (27)	4/12 (33)	NS

[a] The remaining same-setting (n = 116) and separate-setting (n = 29) patients were discharged home within 48 h.
[b] In patients considered at high risk for thromboembolism.
[c] Such as dialysis, rehabilitation, and physician/patient preferences.
Abbreviation: NS = not significant.

in either the electrophysiology laboratory (4–22%)[5–7, 9–12] or the operating room (15%).[6] None of the complications was attributable to same-setting procedures, since each has been reported previously in patients undergoing isolated ICD implantation.[5–12] The observed rate of intraoperative hypotension (0.62%), lead dislodgment (1.2%), pocket hematoma (0.62%), pneumothorax (1.2%), and infection (0.62%) is similar to or lower than the rates previously reported.[5–12, 24, 25] It is surprising that pocket hematoma occurred in only one fully anticoagulated patient, even though the majority received IV heparin at the beginning of EPS (within 60 min of ICD insertion) and we routinely resumed anticoagulation therapy within 24 h postoperatively. The single case of infection occurred in an infection-prone (asplenic) patient; although it is unclear whether it was influenced by same-setting procedures, it might be prudent to avoid procedures in the same settings in similar high-risk patients. The one case of probable embolic stroke might have occurred had the procedures been performed separately. Among 778 patients, Rosenqvist *et al.*[25] reported 4 thromboembolic events (1 resulting in death) but, as in other reports,[5–12, 24] there was no specific mention of stroke.

Compared with antiarrhythmic drugs, ICD therapy is clinically beneficial[2–4] and increasingly more cost effective,[26, 27] largely the result of lower complication rates[28] and cost[15–19] of transvenous ICD systems. Our results indicate that for patients deemed ICD candidates based on EPS results, further reduction in cost can be gained by performing both procedures in the same setting. With ICDs being recommended for an increasing number of patient groups,[1–4, 14, 29–31] any effort at curbing the cost of such therapy is of paramount importance. In cases where EPS results are crucial[3, 4, 14, 30, 31] and when, in particular, antiarrhythmic drug therapy is considered suboptimal to ICD therapy,[3, 4] same-setting procedures may be especially relevant.

Limitations

The timing of ICD implantation with respect to EPS was not randomized, thus introducing potential bias in selecting "healthier" patients for same-setting procedures. However, the two groups in fact shared similar clinical characteristics (Table I) and, furthermore, patients who had same-setting procedures were older (65 vs. 58–64 years) and had lower ejection fraction (0.27 vs. 0.29–0.39) than in other ICD series.[5–12, 28] We also did not formally assess patients' satisfaction regarding same-setting procedures; however, during follow-up, none of the patients expressed dissatisfaction with his/her treatment and hospital course.

Conclusions

This study demonstrates that in patients considered candidates for ICD therapy based on EPS results, same-setting implantation of transvenous ICDs is feasible and safe in the majority of patients and could result in lower cost of providing ICD therapy. Therefore, with the patient's consent and after proper discussion of alternative treatments beforehand, it would be reasonable to consider the same-setting approach when, based on EPS findings, ICD therapy is felt to be the best treatment option for a given patient.

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