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Complications Associated With Pectoral Cardioverter-Defibrillator Implantation: Comparison of Subcutaneous and Submuscular Approaches

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Objectives. **The aim of this study was to compare complications in a large cohort of patients undergoing pectoral cardioverter-defibrillator implantation with a subcutaneous or submuscular approach.**

Background. **Pectoral placement of implantable cardioverter-defibrillator (ICD) pulse generators is now routine because of downsizing of these devices. Subcutaneous implantation has been advocated by some because it is a simple surgical procedure comparable to pacemaker insertion. Others have favored submuscular insertion to avoid wound complications. These surgical approaches have not been compared previously.**

Methods. **The subjects for this study were 1,000 consecutive patients receiving a Medtronic Jewel ICD at 93 centers worldwide. Cumulative follow-up for all patients was 633.7 patient-years, with 64.9% of patients followed up for ≥6 months. The complications evaluated were erosion, pocket hematoma, seroma, wound infection, dehiscence, device migration, lead fracture and dislodgment.**

Results. **Subcutaneous implantation was performed in 604 patients and submuscular implantation in the remaining 396. The median procedural times were shorter for subcutaneous implantation ($p = 0.014$). In addition, the cumulative percentage of patients free from erosion was greater for subcutaneous implantations ($p = 0.03$, 100% vs. 99.1% at 6 months). However, lead dislodgment was more common with subcutaneous implantations ($p = 0.019$, 2.3% vs. 0.5% at 6 months) and occurred primarily during the first month postoperatively. Overall, there were no significant differences in cumulative freedom from complications between groups (4.1% vs. 2.5%, $p = 0.1836$).**

Conclusions. **Subcutaneous pectoral implantation of this ICD can be performed safely and has a low complication rate. This approach requires a simple surgical procedure and, compared with the submuscular approach, is associated with shorter procedure times and comparable overall complication rates. However, early follow-up is important in view of the increased lead dislodgment rate.**

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The implantable cardioverter-defibrillator (ICD) has become standard therapy for the treatment of life-threatening ventricular arrhythmias (1–3). Over the past several years, the implantation technique has evolved considerably. With the development of integrated lead systems and the improvement of shock waveforms, nonthoracotomy and now transvenous implantation have become standard (4–9). Such approaches reduce the morbidity, mortality and costs of ICD placement compared with traditional epicardial techniques (10–13). More recently, sufficient downsizing of pulse generators has been achieved to allow pectoral implantation. This downsizing further simplifies the implantation procedure by avoiding the need for tunneling to the abdomen. In addition, defibrillation efficacy is enhanced because the pectoral pulse generator can serve as part of the defibrillation pathway (14,15).

Although transvenous pectoral implantation has rapidly become the standard technique for initial ICD placement, controversy persists regarding the best surgical approach. Placement of the pulse generator in the subcutaneous tissue of the upper chest, superficial to the pectoralis muscles, is feasible and allows implantation comparable to permanent pacemaker insertion (16,17). This approach permits wide dissemination of this technology and most likely reduces costs by minimizing the need for general anesthesia and the use of operating rooms. However, the present generation of ICD pulse generators is significantly larger (68 to 83 cm^3) than present pacemakers and comparable in size to early pacemakers that were subject to frequent wound complications, including erosion (18,19). This observation has led some to advocate routine submuscular placement, which is a more complicated procedure (20–22). This approach involves transecting the pectoralis major muscle or the use of multiple incisions to tunnel below the muscle. No direct comparisons of the subcutaneous and submuscular implantation techniques have been performed. Accordingly,

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the present study evaluated 1,000 consecutive patients undergoing initial pectoral ICD placement utilizing one or the other of these approaches.

Methods

The subjects for this study were obtained from the data base of Medtronic, Inc. and include 1,000 consecutive patients receiving a Jewel ICD (models 7219D, 7219B and 7202D pulse generators) implanted in the pectoral position. These devices have a pulse generator shell with a weight of 132 g and a volume of 83 cm^3. This study was restricted to all initial implantations that were performed between September 1993 and March 1995 at 93 centers worldwide during the investigational phase of this device. Written informed consent was obtained from each patient, and the study was approved by the institutional review boards of the participating centers. Demographic and implantation data were obtained from standardized forms completed and forwarded to the sponsor for inclusion in the data bank. *Implantation time* was defined as the time from the initial incision to final wound closing.

A variety of lead combinations were used to meet the implantation criteria of a defibrillation threshold ≤24 J required by investigational protocol. All patients received a right ventricular lead (model 6936) for bipolar sensing, pacing and shock therapy. The other leads used were a superior vena cava or coronary sinus coil (model 6933) and a subcutaneous patch (model 6963). The choice of lead system, pulse generator and implantation technique (i.e., subcutaneous vs. submuscular) was at the discretion of the implanting physician. All pulse generators and leads were manufactured by Medtronic, Inc.

After device implantation, patients were evaluated at 1 month, 3 months and every 3 months thereafter. At each follow-up visit, standardized forms were completed. For study purposes, a *complication* was defined prospectively as an event identified by the investigator that required invasive surgical intervention. Complications evaluated were erosion, pocket hematoma, pocket seroma, wound infection, wound dehiscence, device migration, lead fracture and lead dislodgment.

Data analysis. Comparisons were made between the subcutaneous and submuscular groups. Data are shown as mean value ± SD, unless otherwise indicated. For continuous variables, the Wilcoxon rank-sum nonparametric test was used because of skewness of the distribution of the variables. For discrete variables, the continuity-adjusted chi-square test was used. Kaplan-Meier methods were used to estimate the cumulative percentage of patients free from complications over time. Comparisons between the cumulative event-free curves were made using the log-rank statistic. Stepwise Cox regression methods were used to examine the association of risk factors with the time to first occurrence of complications. A p value <0.05 was considered statistically significant.

Results

Patients. The clinical characteristics of the patients are shown in Table 1. The subcutaneous and submuscular implantation groups were well matched, and there were no significant differences in any of the clinical variables evaluated.

Table 1. Clinical Characteristics of 1,000 Study Patients

	Subcutaneous Implantation (n = 604)	Submuscular Implantation (n = 396)	p Value
Age (yr)	60.5 ± 12.1	60.2 ± 13.5	0.758
Male	82.0	82.8	0.787
Ejection fraction	33.6 ± 13.5	33.0 ± 13.9	0.400
Coronary artery disease	71.7	69.4	0.473
Congestive heart failure	22.8	20.7	0.471
Previous cardiac surgery	33.9	36.4	0.473
History of sudden death	37.9	39.4	0.686

Data presented are mean value ± SD or percent of patients.

ICD implantation. Of the 1,000 patients who underwent implantation at the 93 centers, subcutaneous implantation was performed in 604 patients (60.4%), whereas the remaining 396 (39.6%) underwent submuscular implantation. At 27 centers (29%), only subcutaneous implantations were performed, which accounted for 30% (178) of all such procedures. Conversely, at 23 centers (24.7%), only submuscular procedures were performed, accounting for 23.5% (93) of all submuscular procedures. The remaining 43 centers performed both subcutaneous and submuscular implantations and contributed 729 (72.9%) of the total cohort evaluated.

A variety of lead systems were used in this study. All patients had a right ventricular lead for sensing, pacing and shock therapy. The most common lead configuration used was a two-lead right ventricular/superior vena cava system. This configuration was used in 785 patients (78.5%). Three-lead systems were used in 75 (12.5%) of subcutaneous implantations and 65 (16.5%) of submuscular implantations ($p = 0.091$). The three-lead system included a subcutaneous patch in 89% of patients (124 of 140), whereas three coils were used in the remaining 11% (16 of 140) of patients.

Procedural and body habitus characteristics are presented in Table 2. Patients undergoing subcutaneous implantation were significantly heavier (82.6 ± 16.3 kg vs. 79.8 ± 17.3 kg, $p = 0.0053$) and had a larger body mass index (27.1 ± 5.2 vs. 26.1 ± 5.1, $p = 0.0018$) than those undergoing a submuscular approach. There were no significant differences in patient height.

Procedural implantation times were 113 ± 57 min for subcutaneous implants and 120 ± 57 min for submuscular

Table 2. Procedural Variables

	Subcutaneous Implantation (mean ± SD)	Submuscular Implantation (mean ± SD)	p Value
Procedural time (min)	113 ± 57	120 ± 57	0.015
Weight (kg)	82.6 ± 16.3	79.8 ± 17.3	0.005
Height (cm)	174.7 ± 9.6	174.4 ± 10.2	0.833
Body mass index	27.1 ± 5.2	26.1 ± 5.1	0.002

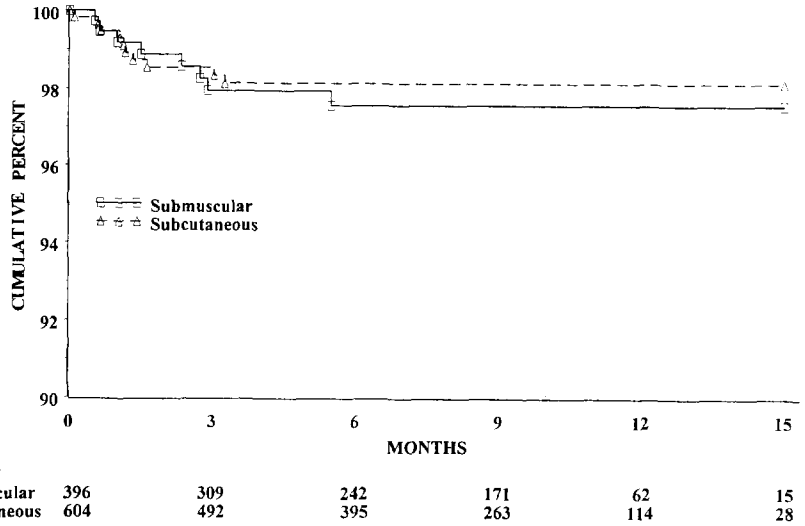

Figure 1. Product-limit estimates of the freedom from a pocket-related complication. Cumulative percentage of patients without complications is shown for the two groups. p = 0.639 for between-group comparisons.

implants. Median implantation times were significantly shorter with the subcutaneous technique (95 vs. 110 min, p = 0.014). As expected, the median implantation time for three-lead systems was longer than for two-lead systems (140 vs. 92 min, p < 0.001). To assess whether the longer procedural times associated with submuscular implantations were due to the slightly higher frequency of patch placement, the two-lead systems in the groups were compared. In patients with two-lead transvenous lead systems, median procedural times were still shorter with the subcutaneous technique (90 vs. 105 min, p = 0.026).

Pocket complications. For evaluation of complications, cumulative patient follow-up for all patients was 633.7 patient-years, with 64.9% of patients followed up for ≥6 months. Comparisons of six-pocket related complications were performed: skin erosion, pocket hematoma and seroma, wound infection and dehiscence and device migration. Only the incidence of skin erosion differed between groups with more erosions (three vs. none) observed with submuscular implantation. These three erosions occurred 0.5, 0.6 and 5.5 months after implantation. The cumulative percentage of patients free from erosion differed between groups (p = 0.03), with estimates at 6 months of 100% for subcutaneous implants and 99.1% for submuscular implants. It is noteworthy that only two serious wound infections (0.2%) developed in this cohort of patients, both of which occurred after subcutaneous implantation.

The overall risk of experiencing any pocket-related complication was compared for the two groups. As shown in Figure 1, there were no significant differences in the cumulative percentage of patients free from complication during any period of follow-up (p = 0.639). At 6 months, complication-free survival was 98.1% for the subcutaneous group and 97.6% for the submuscular group.

Analysis of clinical risk factors indicated that only patient age was associated with pocket complications (p = 0.038). The risk of a complications decreases by ~3.5% for each 1-year increase in age. Body weight or size did not correlate with overall pocket complications.

Lead complications. Lead complications occurred more commonly in the subcutaneous group. Dislodgments were noted in 15 patients in this group and was primarily due to right ventricular lead dislodgment, which occurred in 14 patients (2.3%). In contrast, only two dislodgments (0.5%) developed in the submuscular group, both of which also involved the right ventricular lead. The vast majority of dislodgments in the subcutaneous group occurred early in the first postoperative month. Subsequently, only occasional dislodgments were noted in both groups. Lead fractures occurred infrequently, with three fractures after subcutaneous implantation and one after submuscular implantation. Thus, there were a total of 18 lead complications (3.0%) in the subcutaneous group and 3 (0.8%) in the submuscular group. The time course of any lead complication (dislodgment or fracture) is shown in Figure 2, demonstrating the lower complication rate with the submuscular approach (p = 0.018). Estimated freedom at 6 months from a lead complication is 99.3% for submuscular implants and 96.9% for subcutaneous implants. Risk factor analysis revealed that only a subcutaneous approach was associated with an increased risk of any lead complication. Neither the number of implantations at a center nor the time period of this clinical trial (i.e., early vs. late) was associated with increased dislodgments, suggesting that they were not due to inexperience with implantation.

When the risk of any complication was analyzed, the higher risk of wound complications in the submuscular group tended to offset the higher risk of dislodgment in the subcutaneous group. Consequently, the overall cumulative freedom from complications did not differ between groups (p = 0.1836). The only clinical factor associated with overall complications was a history of coronary artery disease (p = 0.047). Patients with coronary artery disease have about half the risk of experiencing complications.

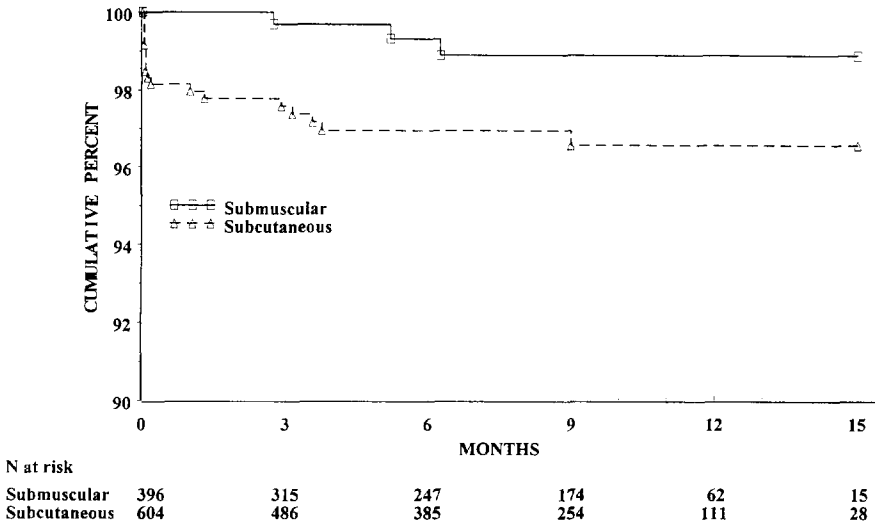

Figure 2. Product-limit estimates of freedom from a lead-related complication. Cumulative percentage of patients without complications is shown for the two groups. p = 0.018 for between-group comparisons.

Discussion

With the downsizing of ICD pulse generators and the development of active can lead systems, pectoral implantation has become standard for initial ICD placement. However, the optimal pectoral surgical technique has not been established. The major finding of the present study of 1,000 consecutive patients is that both subcutaneous and submuscular implantation techniques are associated with comparable overall complication rates, but a shorter procedural time is achieved with the subcutaneous approach.

Comparison with previous studies. Previous studies of small groups of patients have established that subcutaneous or subpectoral placement of modern ICD pulse generators and lead systems is feasible, but no previous comparative studies have been published. The simplicity of the pectoral approach has been emphasized (16,17) and may result in reduced operating room and general anesthesia requirements. In addition, the simpler surgical approach would, with appropriate training in electrophysiology, permit implantation by those who implant permanent pacemakers. The submuscular approach has been advocated by others (20–22) to reduce the morbidity associated with ICD pulse generators, which are significantly larger than modern pacemakers. Older generation pacemakers of comparable size to ICD pulse generators had a significant risk of erosions and other pocket complications (18,19). However, differences in pulse generator shape and patient characteristics makes extrapolation of these results to ICD implants difficult.

Complications. The increased erosion rate for submuscular implantation was surprising. However, this finding must be interpreted with caution because only three erosions were observed, all within 6 months of implantation. It is possible that these erosions were due to a selection bias because patients undergoing submuscular implantation weighed less and had a smaller body surface area. Probably more important is the lack of erosions noted in the subcutaneous group despite follow-up data for 604 patients. The overall incidence of pocket complications was low and did not differ between the two implantation techniques. Of note, with the sample size evaluated, this study had a power of 86% to detect a 6% difference in complication rates at 1 year.

Lead dislodgment was more common with subcutaneous implantation and predominately involved the right ventricular active fixation lead. The dislodgment rate observed (2.3%) was within the range reported previously for similar leads tunneled to an abdominal pocket (5,8,23,24). Dislodgment problems in the past have been attributed to inadequate lead anchoring in the pectoral region (5,25). Dislodgments were unlikely to be due to inexperience with implantation because these events were not related to the number of implantations at a center and did not preferentially occur early in the study. Explanations for the different dislodgment rates include the possibility that the submuscular pulse generator position better stabilized the lead; that better anchoring technique was used with submuscular implants; or that the relatively heavy weight and movement of the pulse generator in the subcutaneous position contributed to lead instability. These possibilities cannot be differentiated from the present data.

The infection rate in this series was very low (0.2%). Previously, infection rates of 1.3% to 2.7% were reported (12,26) from other large multicenter trials of nonthoracotomy ICD implantation in the abdomen. These findings support the notion that the higher infection rates consistently noted with ICD compared with pacemaker implantation are due to the use of an abdominal pocket.

Limitations of the study. The present study must be interpreted in light of certain methodologic limitations. The choice of implantation technique was not randomized or controlled and is thus subject to bias. Although the two groups were well matched clinically, patients in the subcutaneous group weighed on average 2.8 kg more than those in the submuscular group. This difference suggests that some subjects of small body

habitus may have been excluded from subcutaneous implantation. However, the very large sample size with >600 patient-years of follow-up and the observation that 72.9% of patients were from centers that performed both techniques indicate that these results are most likely representative of clinical practice. Moreover, body size did not correlate with complications.

A second limitation is that long term follow-up is limited, particularly >1 year. Accordingly, it is possible that other complications will be noted after several years of observation. However, with follow-up ≥6 months or more available for 649 patients, accurate estimates of complications during this time frame can be ascertained.

Conclusions. This study demonstrates that subcutaneous pectoral implantation of an ICD system with an 83-cm^2 pulse generator can be performed with a low rate of complications. This approach requires a simple surgical procedure and is associated with shorter procedural times and comparable overall complication rates compared with the submuscular approach. However, careful attention to anchoring techniques and close, early follow-up is important in view of the 2.3% rate of lead dislodgment that occurred primarily during the first month after implantation. More long-term follow-up is required to assess more accurately other chronic complications, such as those associated with pulse generator replacement as well as late erosions and lead fractures.

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