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Subpectoral Cardioverter-Defibrillator Implantation Using a Lateral Approach

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Abstract. Introduction: **Third-generation cardioverter-defibrillators have revolutionized management of ventricular tachyarrhythmias. Implantation can be performed in the electro-physiology laboratory, with minimal morbidity. Generator size has shrunk to the point that subcutaneous implantation is feasible and safe, even under local anesthesia. The prepectoral technique, however, is associated with increased mechanical stress to the subcutaneous tissue and can predispose to device erosion or infection. These complications may be avoided by submuscular placement. Among subpectoral techniques, the lateral approach offers unrestricted ability to deploy patches or array electrodes, should the need arise, and may represent the optimal implant technique under some circumstances.**

Methods: **We studied 29 male patients, aged 29–78 years, who presented with syncope or sustained ventricular tachycardia, and underwent subpectoral defibrillator implantation under general anesthesia or conscious sedation. All devices were third-generation active can systems with biphasic shock capability. Six dual-chamber defibrillators were used.**

Results: **Subpectoral implantation was successful in all cases, with an estimated blood loss of 28 ± 17 mL and no immediate complications. Except for one patient who developed twiddler's syndrome and ultimately required revision to a subcutaneous pocket, the implant site was tolerated well, and no limitation in the range of motion of the upper limb was observed during 20 months of follow-up.**

Conclusions: **Subpectoral implantation using a lateral approach is technically straightforward and can be applied globally, with modest additional resource and equipment requirements. Familiarity with this approach can maximize the likelihood of successful defibrillator implantation in the electrophysiology laboratory.**

Key Words. **implantable cardioverter-defibrillators, implantation technique, submuscular**

Introduction

Development of third-generation implantable cardioverter-defibrillators (ICDs) and transvenous lead systems has had a dramatic impact on the management of ventricular tachyarrhythmias. Modern generators with an active shell, biphasic shock capability and optimized electrode design [1,2], can be implanted in the electrophysiology laboratory with a 98% success rate, 1% mortality and low incidence of immediate complications [3]. The clinical benefit extends to long-term outcome, as well as total survival [4]. Device therapy has therefore become a first-line treatment option for ventricular tachyarrhythmias [5].

In the current era, complexity of defibrillator implantation is similar to that of modern pacing systems [6]. On the other hand, certain critical differences remain. Pulse generator size, although shrinking at a steady rate, can only be compared to pacemakers from the early days of permanent pacing, when morbidity due to mechanical complications, system erosion or infections, was high [7,8]. Furthermore, it occasionally becomes necessary to implant extravascular electrical components, in order to lower defibrillation energy requirements [9,10], resulting in a procedure that is considerably more complicated than originally planned. Examined from this perspective, an obvious analogy with pediatric pacing comes to mind [11–13].

We present our experience with a technique originally described by Foster [14], which may maximize the likelihood of successful defibrillator implantation in the pectoral position, with a modest increment in terms of cost and procedural complexity.

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Patients and Methods

Patient Selection

We studied 29 consecutive male patients, aged 29 to 78 years, who presented with syncope ($n = 5$) or sustained ventricular tachycardia ($n = 24$). Most had coronary artery disease ($n = 21$); there were four patients with dilated cardiomyopathy, and one each with idiopathic ventricular tachycardia, hypertrophic cardiomyopathy, rheumatic valvular disease and long QT syndrome. Eight patients had undergone revascularization procedures, combined with valve replacement in three cases. Electrophysiologic testing was performed in all, except for five patients who presented with sustained ventricular tachycardia while on empiric amiodarone therapy.

Implantation Technique

Preparation for the Procedure

Implantation was performed in the electrophysiology laboratory, after obtaining written informed consent, with arrangements for general anesthesia or conscious sedation, as judged necessary.

The supine patient is tilted slightly to the right, at a 20-degree lateral decubitus position [14,15]. After securing both arms, so as to avoid brachial plexus injury, external defibrillator pads (Fast-Patch, Physio-Control Corp., Redmont, WA) are attached to the right anterior chest and the region of the left scapula. Continuous monitoring of the electrocardiogram and radial artery pressure is initiated, and intravenous cefapirin or vancomycin administered for antimicrobial prophylaxis. The anterior chest and upper abdomen are scrubbed with povidone, and the surgical field delineated with a sterile drape (Barrier C-V/Incise Sheet, Johnson & Johnson Medical, Inc., Arlington, TX).

Electrode Implantation

A 3-cm-long incision is made along the left deltopectoral groove. Subsequently, a hydrophilic guide wire (HiGlide, Laboratoires Nycomed, S.A., Paris, France) is advanced to the right heart, through a small cephalic venotomy, or after cannulation of the subclavian vein using the modified Seldinger technique. The defibrillation lead is inserted through a peel-away introducer and positioned at the right ventricular apex. When adequate pacing parameters have been obtained, the lead is secured on the pectoralis major using nonabsorbable sutures that form an omega-shaped stress-relieving loop. Atrial electrodes are implanted using a similar approach and the retained guidewire technique.

The Subpectoral Device Pocket

After securely attaching the leads, a 5-cm-long incision is made from the lateral border of the breast with an inferolateral orientation (Fig. 1). This incision allows immediate access to the lateral border of the pectoralis major, at a safe distance from the lateral thoracic artery. The device pocket is formed by bluntly dissecting between the pectoralis major and the ribs [14]. As the submuscular space is devoid of large vessels, it can be expanded safely using the index finger [15].

Occasionally, electrocautery is necessary (Hyfrecator Plus, Birtcher Medical Systems, Irvine, CA) in order to achieve adequate hemostasis. Significant bleeding is rare, however, since the pectoralis major proper is not dissected. Once the subpectoral device pocket has been formed, a curved clamp is used to tunnel the leads (Fig. 2) through a 28 F thoracostomy tube (Argyle Thoracic Catheter, Sherwood Medical, Tullamore, Ireland) that accommodates their distal connectors. At this point, fluoroscopy and pacing measurements have to be repeated, in order to detect possible lead dislodgment. The leads are attached to the pulse generator which is bathed in a gentamicin solution and placed in the submuscular pocket. Any lead slack present is shifted just lateral to the pocket (Fig. 3), so as to avoid compression between the generator and the ribs [16]. A woven nonabsorbable suture placed between the pectoralis major and serratus anterior fascia, seals the neck of the pocket. Both incisions are closed in layers, using absorbable sutures, and the guide wire is removed after assessing the system for adequate defibrillation.

Intraoperative Defibrillation Testing

During wound closure, the pulse generator performs device-based defibrillation testing. If the default configuration is ineffective, the following modifications are made: reversal of the vector polarity [17], electrode repositioning and, if necessary, addition of other intravascular or subcutaneous electrodes. The lateral incision allows easy access to the underside of the latissimus dorsi muscle, where a lead array can be placed pointing posteriorly [9,14].

Results

Device Implantation

Submuscular implantation was successful in all cases, using active can biphasic generators, six of which had dual-chamber pacing capability. Access to the cephalic vein was achieved in 18 (62 %) patients. Mean R-wave amplitude measured 10 ± 4 mV and pacing threshold was

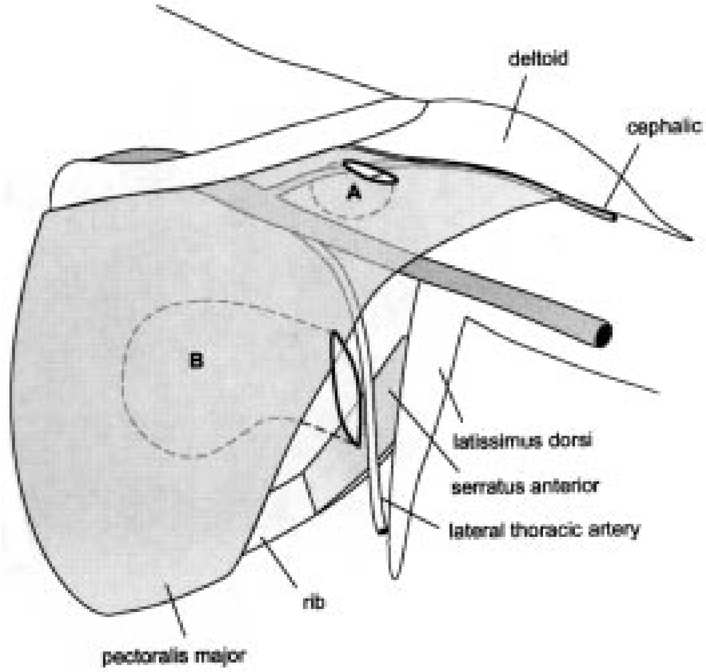

Fig. 1. *Anatomic landmarks of the anterior chest venous access is acheived through a small subclavian incision (A), while the pulse generator is implanted in a submuscular pocket (B). Note the course of the lateral thoracic artery, just lateral to the pocket incision. Subcutaneous patches or array electrodes can be implanted in any direction, if necessary, through the same incision.*

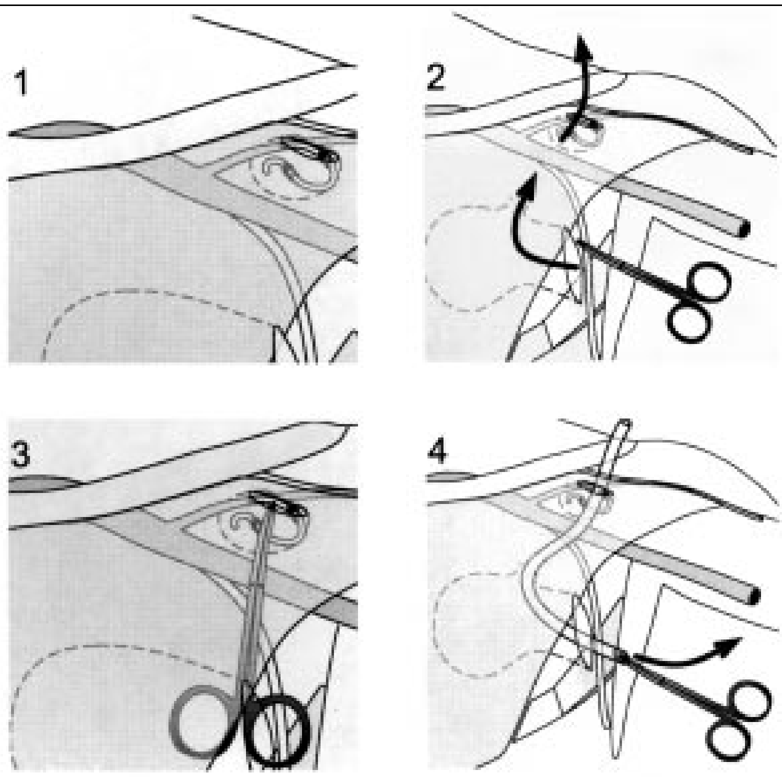

Fig. 2. *Tunneling technique. After anchoring the electrode on the pectoralis major (step 1), a hemostatic clamp is used to create a tunnel between the subclavian and the submuscular pockets (steps 2–3). The clamp then grabs a thoracostomy tube, where the lead connectors are placed, and the tube-electrode assembly is withdrawn into the generator pocket (step 4). The importance of the omega-shaped stress relieving loop, to ensure electrode stability, cannot be overemphasized.*

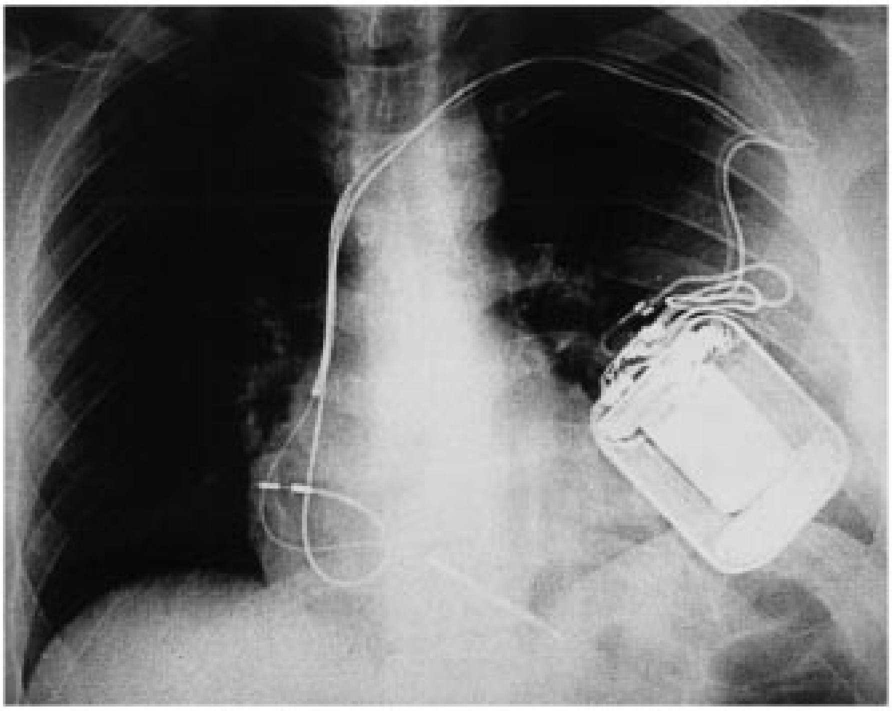

Fig. 3. Anteroposterior chest radiograph after a submuscular dual-chamber defibrillator implant. Note the "omega" loop at the site of electrode attachment, and the placement of lead slack just lateral to the pulse generator.

0.5 ± 0.1 V, at a pulse width of 0.5 ms. Defibrillation testing at an initial energy setting of 18 ± 3.5 J was performed and was universally successful; no patches or lead arrays were implanted.

All patients were awake and breathing spontaneously at the end of the procedure. Intraoperative blood loss ranged between an estimated 10 and 60 mL (mean 28 mL). The few patients requiring anticoagulation received intravenous heparin six hours after the procedure, and their maintenance warfarin dose on the same evening.

Immediate Complications

One patient developed a small left lung atelectasis, which was managed with antimicrobial therapy and pulmonary physiotherapy. There was one case of rapid atrial fibrillation which responded to antiarrhythmic drugs. No pocket hematomas or other surgical complications were seen.

Clinical Outcome

Patients were discharged on the fourth (range 1–14) postoperative day. Follow-up extended from 3 to 33 months, with two nonarrhythmic deaths during that period. Five patients were hospitalized with congestive heart failure, and three developed ventricular tachycardia storms. Overall, 12 ambulatory patients (40 %) developed recurrent ventricular arrhythmias, which were treated appropriately by their device.

The implant site was well tolerated by all, and no limitations in the range of motion of the upper limb were observed. The cosmetic result was quite satisfactory (Fig. 4), while there were no instances of telemetry difficulty or myopotential interference.

Long-term Complications

One patient developed a superficial infection at the subclavian incision, four weeks after the procedure. It was treated conservatively, with an extended course of intravenous antimicrobial therapy. In another patient, swelling of the left arm developed ten months post implantation, and digital angiography confirmed the presence of subclavian vein thrombosis. Once again, management was conservative, with resolution of the findings after a course of oral warfarin.

A young patient with a dual-chamber device had painless swelling of the submuscular pocket, which was attributed to twiddler's syndrome. The unit was reimplanted subcutaneously, without incident.

Discussion

In its beginning, automatic defibrillation using implanted devices represented a solution of last resort for patients with recurrent ventricular tachyarrhythmias and documented resistance to pharmacological therapy. Epicardial implantation

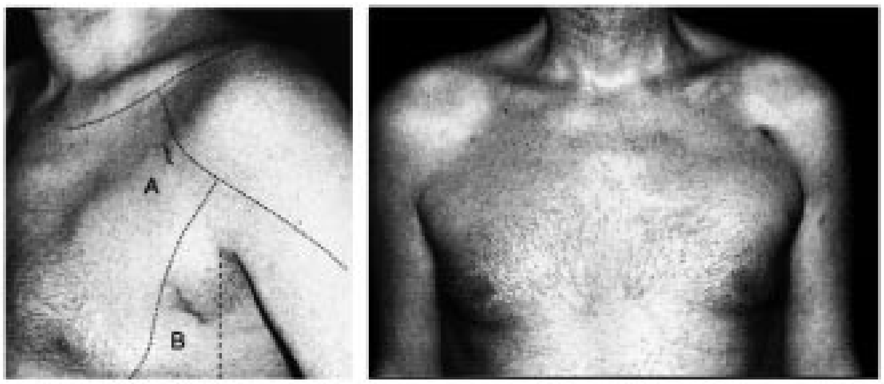

Fig. 4. *Pocket appearance, two weeks post implant. Note the relationship of the surface landmarks and the lateral incision (left panel), which allows easy access to the submuscular space, with a satisfactory cosmetic result (right panel).*

through a median sternotomy, lateral or subxiphoid thoracotomy was universally necessary [18]. Early pulse generators had a volume of > 140 cc, requiring implantation in the abdomen, usually under the rectus muscle. Protection from tachyarrhythmic sudden death for that highly selected patient population, was offset by the significant surgical risk, and a periprocedural mortality approaching 3 % [3,19]. Furthermore, system malfunction was not uncommon, as were reoperations to correct mechanical component damage [20].

Development of transvenous lead systems has gradually brought ICD implantation to the electrophysiology laboratory, inaugurating the modern era of nonpharmacological therapy for ventricular tachyarrhythmias [6]. Currently, ICD implantation carries less than 1 % mortality risk, with low incidence of perioperative morbidity. It is also considerably more cost-effective [3]. Evolution of third generation devices with an active shell and biphasic shock capability, represents the latest milestone in implantable device technology. The global acceptance of ICDs as a first-line treatment that essentially eliminates arrhythmic sudden death, can probably be attributed to these systems [2].

The Importance of Implantation Technique

The majority of modern nonthoracotomy systems are implanted subcutaneously in the left anterior

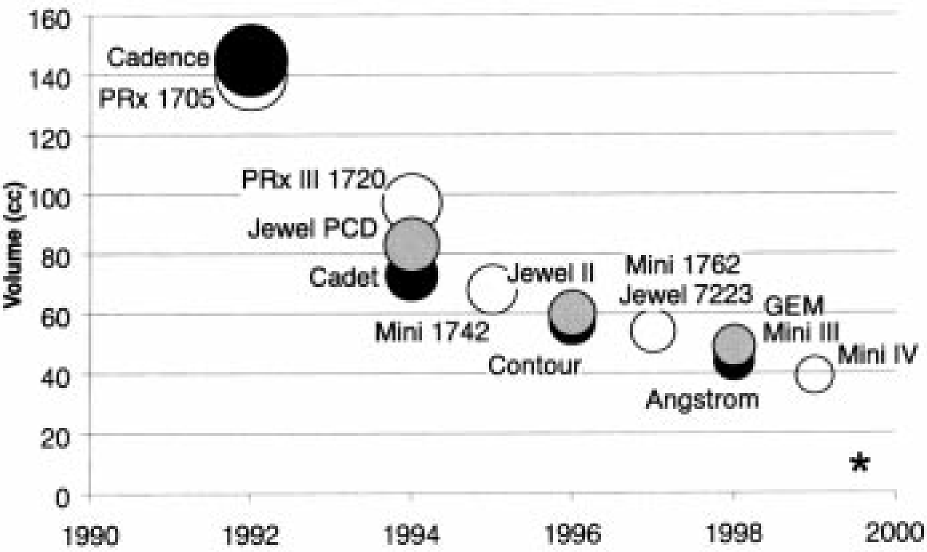

Fig. 5. *Gradual reduction in pulse generator size during the past decade. Third-generation devices have become significantly smaller, while at the same time retaining features, as well as their maximal energy output. Pectoral implantation was virtually impossible before 1993, because most devices in clinical use were of prohibitive size. Even now, dual-chamber defibrillators (not shown) remain quite bulky. For comparison, a modern dual-chamber pacemaker has a volume of less than 15 cc (asterisk). (white disks = CPI Guidant, Corp., grey disks = Medtronic, Inc., black disks = Ventritex, Inc.)*

chest, usually under local anesthesia [21,22]. Originally described by Stanton [23], it is an approach that enjoys widespread acceptance to this day, at times with minor variations [24]. Certainly, it represents complete convergence with pacemaker implantation, requiring virtually no additional equipment or modifications to the technique. Indeed, the subcutaneous approach becomes even more attractive, as pulse generator size continues to shrink steadily (Fig. 5). The absolute size of a typical defibrillator unit, however, remains quite bulky, and can be up to five times larger compared to a dual chamber pacemaker. From this perspective, the pacemaker analogy more accurately reflects the early days of transvenous permanent pacing, or, by extension, modern pediatric pacing.

Based on clinical data from the early pacing literature, subcutaneous implantation of large generators carries a significant risk of device erosion and infection [8,25]. Mechanical stress to the overlying skin is obviously greater in patients with small or cachectic build, in whom formation of a subcutaneous pocket may be difficult. As for children, the analogy with small adults is also reflected on the complications of permanent pacing [11]. Gillette has outlined the role of submuscular generator implantation in pediatric pacemaker recipients [12].

There is yet another point where the pacemaker analogy falls apart. Contrary to transvenous pacemakers, an ICD system occasionally requires addition of extravascular components to improve defibrillation efficacy [9,10,26]. Subcutaneous patches or lead arrays are commonly used to alter the defibrillation vector, when the unit cannot defibrillate reliably in its default configuration. In the past, subcutaneous patch implantation was necessary in up to one third of all procedures [27]. This, of course, is no longer the case, as unipolar—"active can"—designs have radically improved the energy efficiency of modern defibrillators. The likelihood of failure in their default configuration, however, although remote, has not been entirely eliminated [28]. In everyday clinical practice, it is exceedingly difficult and, perhaps, impossible to prospectively identify these outliers.

It therefore becomes necessary to prepare for such a possibility, since subcutaneous electrodes introduce an added layer of complexity, as well as risk. The presence of a subcutaneous patch increases the relative risk of infection by an odds ratio of 3, compared to entirely transvenous systems [29]. Certainly, unrestricted access of the entire anterior chest, up to the level of the posterior axillary line, is important when the need arises—usually in an unanticipated manner—to implant a patch or lead array. Maximal versatility may be afforded when access to the underside of the pectoralis major or lattissimus dorsi muscles can be obtained.

Choosing any of the available techniques can, therefore, have a direct impact on the likelihood of successful implantation, as well as the procedural morbidity. Furthermore, the relatively short life span of defibrillator units [30] and the higher frequency of generator changes, may perpetuate problems stemming from the primary implant.

Review of Subpectoral Implantation Techniques

Nonthoracotomy ICD implantation in the pectoral position was virtually impossible before 1993, because pulse generators were of prohibitive size. Even with the first pectoral implants, the devices remained quite bulky. For this reason, submuscular placement was initially preferred [27,31], since the risk of erosion had become apparent with subcutaneous abdominal implants [32]. Submuscular implantation has certain advantages (Table 1) including better protection from device erosion [11] and an anticipated reduction in infection risk [8,33].

A number of variations of the submuscular technique have been described, of which the anterior approach, through a long subclavicular incision, enjoys the wider acceptance and is probably the most straightforward. This approach requires separation of the sternal and clavicular heads of the pectoralis major, in order to form the generator pocket [34]. It thus allows convenient entry into submuscular space, through the same incision used for venous access. Despite its simplicity, however, the anterior approach has a number of shortcomings. Blunt dissection of the pectoralis major increases the hemorrhagic risk, while making surveillance of the surgical field more difficult [27]. In an area brimming with vessels and nerves, the chances of mechanical injury during the procedure may be significantly higher [14]. Paradoxically, submuscular placement of the generator may predispose to twiddler's syndrome [14,35].

In the early days of submuscular pectoral implants, a number of modifications were developed, in order to optimize patch placement [36]. Variants of the technique have also been described, for use under special circumstances, like submammary implantation in women [37]. While formal comparison among the implantation methods has never been attempted, a sizable body of multicenter experience was accumulated during clinical trials of early third generation systems. Gold, representing the Worldwide Jewel Investigators [38], studied 1,000 patients who underwent transvenous implantation of the Medtronic Jewel defibrillator in the pectoral posi-

Table 1. *Three pectoral implantation techniques compared*

	Subcutaneous Implantation	Submuscular Implantation	
PROS	– similar to pacemaker implantation; does not require major modifications to the technique or special training – conventional equipment requirements – can be performed under local anesthesia with conscious sedation – single incision	– good protection of the system from mechanical stress, especially in patients with small or cachectic build, possibly with reduced infection and erosion risk – the generator does not interfere with breast tissue – straightforward implantation of extravascular components (patches or arrays)	
	– enjoys wide acceptance – shortest procedure times	*Anterior approach*	*Lateral approach*
		– requires a single incision	– easier hemostasis – better cosmetic result in women
CONS	– requires formation of a large subcutaneous pocket, which may be difficult in small or cachectic patients – mechanical stress to the overlying skin and potential erorion risk – protrusion of the device	– relatively complex, requires significant modifications to the implantation technique – not as widely used – increased equipment requirements (suction, surgical cautery) – longer procedure times	
	– twiddler syndrome risk?	*Anterior approach*	*Lateral approach*
	– proximity with breast tissue in women of reproductive age who require periodic mammography	– often requires general anesthesia – requires separation of the pectoralis muscle, which may predispose to bleeding and nerve injury – increased brachial plexus injury risk?	– often requires general anesthesia – requires two incisions, as well as tunneling of the lead(s) – access to the cephalic vein is more difficult through the small subclavian incision – postoperative pain and analgesic requirements

tion. No significant differences in total morbidity relating to implantation technique were found in this group. Surprisingly, a higher incidence of lead dislodgement was seen with subcutaneous implants, while system erosion was less frequent, compared to the submuscular technique. These findings may represent a relatively short follow-up, as well as the evolving learning curve of the era.

The Lateral Approach as a Primary Submuscular Implantation Technique

The lateral approach was originally described by Foster [14], in an attempt to retain the advantages of submuscular placement, while avoiding the technical difficulties associated with the anterior approach. Its distinguishing feature is that continuity of the pectoralis major is not disrupted, except during tunneling of the leads. While the risk of vessel injury remains, especially that of the lateral thoracic artery, the orientation of the incision is such that pocket formation can take place under direct inspection, ensuring reliable hemostasis.

In our study, submuscular implantation with a lateral approach was performed without surgical complications, even in the smallest patients with bulky dual-chamber generators. Cannulation of the cephalic vein was successful in about two thirds of the patients, and this obviously reflects the constraints imposed by a small subclavicular incision. Clinical outcome, as well as the final cosmetic result, are in line with modern practice. It, therefore, represents a technique that can be used globally, with modest increments in terms of cost and procedure complexity. Under certain conditions, it may in fact represent the optimal implantation technique.

Limitations of the Study

Our results represent the outcome of a small, yet typical, population undergoing defibrillator implantation. We made no attempt to randomize our approach, so as to detect possible differences among individual techniques. Lastly, two parameters of particular relevance to submuscular implantation were not recorded: total procedure time and analgesic requirements during the early postoperative period. Based on our experience, however, submuscular implantation is slightly more laborious and is associated with increased postprocedural pain, in most cases.

Conclusions

Defibrillator implantation in the pectoral position can be accomplished with a number of methods, each having a unique set of characteristics. As a general rule, submuscular placement may be superior to the subcutaneous approach in small or cachectic patients and, perhaps, women. This appears to be the case despite drastic device miniaturization, as their absolute size remains considerable when compared to modern pacemaker generators.

The lateral approach to subpectoral implantation offers significant versatility in the rare patient who requires extravascular electrodes in order to lower defibrillation energy requirements. It may also be superior to the anterior approach, with respect to the risk of mechanical complications, such as bleeding and brachial nerve injury. These potential advantages, however, have not been validated in a controlled fashion, while they clearly apply to only a small subset of patients referred for defibrillator implantation.

As far as cost and resource requirements are concerned, the increment is relatively modest, except for the occasional need for general anesthesia. Familiarity with this technique may, under certain circumstances, maximize the likelihood of successful defibrillator implantation in the electrophysiology laboratory.

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