



# Conscious sedation during subcutaneous implantable cardioverter-defibrillator implantation using the intermuscular technique

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## Abstract

**Background** The subcutaneous implantable cardioverter-defibrillator (S-ICD) system is an established therapy for the prevention of sudden cardiac death (SCD) and an alternative to a transvenous implantable cardioverter-defibrillator (ICD) system in selected patients. S-ICDs are usually implanted under general anesthesia. The purpose of the present study was to describe the technical feasibility and safety of local anesthesia with conscious sedation as an alternative to general anesthesia during S-ICD implantation using the intermuscular technique.

**Methods** We conducted a retrospective, single-center study on patients undergoing S-ICD implantation using the intermuscular technique at our center between February 2016 and May 2018. All procedures were performed under controlled sedation with propofol and midazolam. Local anesthesia was used for all procedures.

**Results** Twenty-two patients (17 men and 5 women) with a mean age of  $51.1 \pm 16.2$  years were included. The indication for S-ICD implantation was primary prevention in 18 (81.8%) patients. The mean dose of midazolam and propofol administered was  $7.8 \pm 2.3$  mg and  $72.7 \pm 37.4$  mg, respectively. The procedural success rate was 100%, with no apneic or hypoxic episodes or other complications requiring therapeutic intervention. None of the patients required conversion to general anesthesia. All patients were comfortable with the position and appearance of the device.

**Conclusions** Our findings suggest that local anesthesia with conscious sedation using propofol and midazolam is a safe and feasible option for S-ICD implantation procedures using an intermuscular technique.

**Keywords** S-ICD · Intermuscular technique · General anesthesia · Safety · Sedation · Sudden cardiac death

## Abbreviations

ASA	American Society of Anesthesiologists
AST	Automated screening tool
CIED	Cardiac implantable electronic device
DFT	Defibrillation threshold
ICD	Implantable cardioverter-defibrillator
IVF	Idiopathic ventricular fibrillation
J	Joule
M	Musculus
RASS	Richmond Agitation-Sedation Scale
SCD	Sudden cardiac death
S-ICD	Subcutaneous implantable cardioverter-defibrillator
VF	Ventricular fibrillation

## 1 Introduction

The use of a conventional transvenous implantable cardioverter-defibrillator (ICD) is an established therapy for the prevention of sudden cardiac death [1–6]. Frequent complications associated with conventional ICDs involve the transvenous leads. Transvenous lead-related complications include serious events such as pneumo- and hemothoraces, cardiac perforation with pericardial effusions, and systemic infections. A totally subcutaneous implantable cardioverter-defibrillator (S-ICD Cameron Health/Boston Scientific) was developed as an alternative treatment option in prevention of sudden cardiac death. Regardless of the pacing-related limitations, young patients at risk of ventricular fibrillation (VF) and those with limited vascular access, congenital heart diseases, or infections of the transvenous ICDs are excellent candidates for receiving an S-ICD [7–9]. The pulse generator of the S-ICD has a large volume in comparison to a conventional ICD. The initial real subcutaneous implantation technique was associated with high rates of pocket complications, e.g., infections or

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skin erosions [8–11]. Therefore, a modified intermuscular pocket implantation technique was developed. Placement of the generator between the muscles serratus anterior and latissimus dorsi seems to result in fewer complications and improves the cosmetic results and patient comfort. Accordingly, to improve defibrillation efficacy and optimize the defibrillation vector the surgical placement of the generator is very important and a dorsal and intermuscular placement is needed to capture more ventricular mass between the pulse generator and the shocking coil for efficient defibrillation. At the beginning of the era of S-ICD implantations, procedures frequently required patients to be under general anesthesia because of the large pocket preparation, extensive lead tunneling, and induction VF for defibrillation threshold (DFT) testing [10, 12, 13]. Nowadays, there are several anesthesia modalities used [14], but still there is no consensus on the preferred type of anesthesia for patients undergoing S-ICD implantation. The aim of this study was to summarize the experience of a single-center in evaluating the feasibility of local anesthesia with conscious sedation for S-ICD implantation using the intermuscular technique.

## 2 Methods

### 2.1 Patients

Twenty-two patients aged > 18 years in whom an S-ICD (Boston Scientific, Natick, MA) was implanted between February 2016 and May 2018 were included in the retrospective study. We routinely recorded data to evaluate the safe and effective management of all patients. The study was performed in accordance with the 1975 Declaration of Helsinki and approved by our ethical review board (Ethics committee of the University of Duisburg-Essen, 17-7701-BO). After written informed consent, was obtained, all parameters were entered into an internet-based electronic case report from the center. Patient records were de-identified and analyzed anonymously.

### 2.2 Implantation procedures

Patients were first screened preoperatively with an automated screening tool (ATS) by considering electrograms in each of the three sensing vectors. Before the procedure, a demonstration electrode has been fixed 1-cm left of and lateral to the sternum with the proximal ring placed 1-cm superior to the xiphoid process. A demonstration pulse generator was also attached at the level of the fifth to sixth inter-costal space and the mid-axillary line. The optimal positions of the shocking coil and the pulse generator were governed by the position of the heart within the chest. Under fluoroscopic guidance of 30 frames per second, we reviewed the relative positions of

the shock coil and pulse generator was controlled to maximize the ventricular mass between the two. Pulse generator outline and incisions were then marked on the skin. All S-ICD implantation procedures were performed in a hybrid operating room under standard sterile conditions. Patients were placed in the supine position with their left arm positioned away from the body to allow access to the lateral chest. Prophylactic antibiotic therapy (cephazolin i.v.) was administered 30 mins before and S-ICD implantation was performed using the two-incision technique [15] and the intermuscular pocket approach between m. serratus anterior and m. latissimus dorsi as described previously [16]. The generator pocket incision, slightly curved, overlay the fifth to sixth intercostal space 4 cm lateral to the mid-clavicular line toward the mid-axillary line. The lead was tunneled subcutaneously from the generator pocket into a small incision at the inferior edge of the xiphoid process.

S-ICD surgery was performed under conscious sedation with local anesthesia. The sedation depth was evaluated according to purely clinical parameters based on the Richmond Agitation-Sedation Scale (RASS). We evaluated the patients if they were awake and calm and if they responded to voice or any physical stimulation. During the whole procedure, continuous monitoring of the respiratory rate, blood pressure, heart rate via ECG monitoring, and oxygen saturation was performed. No preoperative administration of pharmacological agents despite prophylactic single-shot antibiotics was performed. Local anesthesia was performed by local infiltration along the entire path of lead and around the pocket using 40–60 ml of Scandicain 2%. Conscious sedation was achieved with a combination of midazolam and propofol without the involvement of an anesthesiologist. This was performed with a combination of midazolam (15–30 µg/kg) and a standard initial dosage of 30 mg propofol followed by a propofol infusion in all patients with a minimum infusion rate of 30 µg/kg/min. Three patients received fentanyl (0.5–1.5 µg/kg) administered intravenously at the start of the procedure with continuous monitoring of blood pressure, oxygen saturation, and heart rhythm. An arterial access was regularly required for continuous blood pressure monitoring and was documented in 3 to 5-min intervals. If no arterial line was required, blood pressure was measured noninvasively with an upper arm cuff device on an intermittent basis at 3-min intervals and documented. Blood pressure data for the LVAD patient was collected by an invasive blood pressure monitoring using an arterial access and measuring and documenting the MAP. Supplemental oxygen was administered with a simple facemask. The baseline MAP recorded before initiation of sedation was compared with the lowest intra-procedural value. At the end of the procedure, defibrillation threshold testing was performed under deep sedation in 19 of 20 patients (95%) to assess for successful S-ICD shock conversion of 50-Hz stimulation induced ventricular fibrillation (VF) with

a safety margin of 15 J (J). A successful conversion was defined as the delivery of 65 J with any shock vector with a maximum output of 80 J.

A mean blood pressure of < 55 mmHg and sedation-induced airway compromise requiring endotracheal intubation were considered serious adverse-events.

The primary endpoint was the feasibility of S-ICD implantation in the intermuscular technique under local anesthesia and conscious sedation without the requirement of general anesthesia. As secondary endpoints we evaluated complication rates within the 30-day follow-up period with respect to following minor and major complications: minor complications included pocket hematomas and wound infections when treated conservatively. Major complications included those that lead to re-hospitalization or the need for a surgical intervention.

For follow-up, the patients were examined 4 weeks after the device implantation and in regularly terms on a 3/6-months basis afterwards. During the initial follow-up, we inspected the device pocket with respect to any signs of hematoma, bleeding, swelling, infection, or impaired healing. Furthermore, all relevant device parameters (battery, impedance, vector recognition, and recorded arrhythmia episodes) were evaluated. All patients were asked within the 24 h after the procedure if there was any major discomfort or pain during the procedure (answer options: yes/no).

### 2.3 Statistical and data

Baseline characteristics, procedure-related data, anesthetic data, and procedure-related complications were recorded in a database. Patient tolerability of the procedure was also assessed. All statistical analyses were performed using SPSS version 24.0 (IBM SPSS, Chicago, IL, USA). Continuous variables are expressed as mean  $\pm$  standard deviation in case of normal distribution, and as median and interquartile range in the cases of other types of distribution. Categorical variables are summarized as counts and percentages.

## 3 Results

### 3.1 Patient and procedural characteristics

Baseline characteristics of the patients are listed in Table 1. Between February 2016 and May 2018, 22 patients underwent S-ICD implantation using the two-incision intermuscular technique by a single operator. Mean patient age was 51.1  $\pm$  16.2 years and 17 (77.3%) patients were male. Mean ejection fraction (EF) was 25%  $\pm$  6%. Dilatative cardiomyopathy was present in 8 (36.4%), ischemic cardiomyopathy in 10 (45.5%), and hypertrophic cardiomyopathy in 2 (9.1%) patients. Two patients had idiopathic ventricular

**Table 1** Baseline demographic and clinical characteristics of the study population

Patients	<i>n</i> = 22
<b>Demographics</b>	
Mean $\pm$ SD age at implant, years	51.1 $\pm$ 16.2
<i>n</i> (%) < 35 years	3 (13.6)
Male sex, <i>n</i> (%)	17 (77.3)
Body mass index (kg/m <sup>2</sup> )	28.6 $\pm$ 7.1 (14–45)
<b>Medical history</b>	
DCM, <i>n</i> (%)	8 (36.4)
ICM, <i>n</i> (%)	10 (45.5)
HCM, <i>n</i> (%)	2 (9.1)
IVF, <i>n</i> (%)	2 (9.1)
CABG, <i>n</i> (%)	0 (0)
Coronary artery disease, <i>n</i> (%)	12 (54.5)
Left ventricular ejection fraction (%)	25.9 $\pm$ 6
Atrial fibrillation, <i>n</i> (%)	3 (13.6)
Renal insufficiency, <i>n</i> (%)	6 (27.3)
Diabetes, <i>n</i> (%)	7 (31.8)
<b>ASA</b>	
ASA III <i>n</i> (%)	11 (50)
ASA IV <i>n</i> (%)	11 (50)
<b>Indication for s-ICD implantation</b>	
Primary prevention of SCD	18 (81.8)
Secondary prevention of SCD	4 (18.2)
No venous access, <i>n</i> (%)	1 (4.5)
Prior sternotomy, <i>n</i> (%)	3 (13.6)

SCD sudden cardiac death, ASA American Society of Anesthesiologists, DCM dilatative cardiomyopathy, ICM ischemic cardiomyopathy, HCM hypertrophic cardiomyopathy, IVF idiopathic centricular fibrillation, CABG coronary artery bypass graft surgery

fibrillation with no overt structural heart disease. Indications for S-ICD implantation were primary prevention in 18 patients (81.8%) and secondary prevention in 4 (18.2%). Only three patients had a history of atrial fibrillation (13.6%), and none of the patients underwent prior cardiac surgery. One patient underwent S-ICD implantation with a left ventricular assist device (LVAD) support. The majority of patients were either receiving anti-platelet therapy or were on oral anticoagulation (Table 2). Four patients (18.2%) were treated with vitamin K antagonists (VKA), while 2 (9%) patients were on non-vitamin-K oral anticoagulants (NOAC). One patient required triple therapy, and 6 (27.3%) patients received dual antiplatelet therapy (DAPT) and 5 (22.3%) were on single antiplatelet therapy (SAPT). Half of the patients had an ASA classification IV (*n* = 11, 50%). Nine patients (40.9%) had a BMI at least of 30 kg/m<sup>2</sup>.

**Table 2** Peri-interventional anticoagulation

Anticoagulation	n (%)
VKA*	4 (18.2)
NOAC	2 (9)
Rivaroxaban	1 (5)
Edoxaban	1 (5)
Apixaban	0 (0)
Dabigatran	0 (0)
SAPT	5 (22.3)
DAPT	6 (27.3)
Triple therapy	1 (4.5)

VKA vitamin K antagonist, SAPT single antiplatelet therapy, DAPT dual antiplatelet therapy, NOAC novel oral anticoagulant

\*Mean INR of patients on VKA at the time of the procedure was  $1.17 \pm 0.32$

### 3.2 Procedural data

A detailed list of procedural data is provided in Table 3. The mean overall procedure duration (time from first skin incision until the end of surgery) was  $39.4 \pm 13.5$  min ranging from a minimum of 18 min to a maximum of 76 min. The mean doses of administered midazolam and propofol were  $7.8 \pm 2.3$  mg and  $72.7 \pm 37.4$  mg, respectively. No patient experienced hypotension or oxygen desaturation during the period of conscious sedation.

**Table 3** Procedure-related data

Total procedure time, minutes	$39.4 \pm 13.5$ (18–76)
Length of postoperative hospital stay, days	$3.0 \pm 1.8$
Perioperative complications, n (%)	0 (0)
Lead dislodgement, n (%)	0 (0)
Superficial infection, n (%)	0 (0)
Significant device-pocket hematoma, n (%)	0 (0)
DFT	20 (91)
MAP max (mmHg)	$89.1 \pm 7.6$ (77–106)
MAP minimal (mmHg)	$66.3 \pm 8.2$ (58–94)
MAP decrease (%)	$35.3 \pm 10.5$
Heart rate (beats/min)	$70 \pm 13$
Oximetric saturation (%)	
Before sedation	$98 \pm 2$
Max deviation during sedation	$93 \pm 2$
Average sedation dosage*	
Propofol (mg)	$72.7 \pm 37.4$
Midazolam (mg)	$7.8 \pm 2.3$

DFT defibrillator threshold test, MAP mean arterial pressure

\*Three patients received fentanyl (0.5–1.5  $\mu\text{g}/\text{kg}$ ) administered intravenously at the start of the procedure

The use of conscious sedation was not associated with significant hemodynamic changes; there was no need for pharmacological interventions. The mean baseline MAP was  $88.3 \pm 7.2$  mmHg. The mean lowest intra-procedure MAP was  $64.2 \pm 4.5$  mmHg.

All patients but one underwent successful VF-induced defibrillation at 65 J shock. The patient with a defibrillation failure underwent external defibrillation with 200 J biphasic shock and, after repositioning of the pulse generator more dorsally, an effective internal shock was obtained in standard polarity.

The mean postoperative hospital stay of the patients was  $3.2 \pm 1.8$  days. No patient developed a significant device-pocket hematoma requiring surgical intervention. There was no case of perioperative (< 24 h) mortality, and no patient died within 30 days. Patients quickly accommodated to the device in the intermuscular position without reporting any discomfort. There were no electrode or pulse generator migrations. There were no procedure-related complications requiring a prolonged hospital stay. Moreover, within the first 30 days, there was no readmission, no bleeding complication, and no wound infection requiring any revision or antibiotics.

### 4 Discussion

Cardiac implantable electronic device (CIED) procedures are increasingly being performed using local anesthesia with conscious sedation rather than general anesthesia. However, a substantial number of S-ICD implantation procedures are still performed under general anesthesia [10, 12]. In particular, device implantation of an ICD or S-ICD into an intermuscular pocket is considered potentially painful, requiring general anesthesia. This retrospective, single-center experience examined the feasibility of S-ICD implantations under conscious sedation. Previous published studies reported cases of S-ICD implantation under the thoracic paravertebral nerve block, combination of transversus thoracic muscular plane block, and serratus plane block without general anesthesia [17–20]. These regional nerve blocks are not the best as the first choice due to different limitations, e.g., a residual number of patients still requiring deeper sedation with propofol or the fact that many patients are anticoagulated or may have a dual antiplatelet therapy which increases the risk of injection-related bleeding complications.

Previous small studies described the use of controlled sedation, anesthetic management, and outcomes in patients undergoing S-ICD implantation [13, 21]. The hypothesis of this study was that even the implantation of S-ICD using the intermuscular technique under controlled sedation is feasible and safe. The patients enrolled in this study were representative of a typical ICD patient population. In clinical practice, the majority of patients with an indication for ICD suffer from

ischemic or dilated cardiomyopathy. This is in line with our data showing ischemic cardiomyopathy in 45.5% and dilated cardiomyopathy in 36.4%. Eighty percent of the patients had a primary indication concordantly with large clinical trials [10, 12], whereas the mean procedure duration was  $40.1 \pm 13.9$  min in our series and shorter in comparison to  $69 \pm 27$  min in the EFFORTLESS Registry [12].

For the safe performance of the procedures, a well-trained staff with experience in airway management is required. An advantage of local anesthesia under conscious sedation is the nonrequirement of a complete anesthetic team. Nevertheless, we ensured that an experienced anesthesiologist or cardiologist with experience in intensive care medicine was present during all procedures, in addition to two nurses with training and experience in airway management and advanced life support. Thus, the presence of at least one individual who was exclusively responsible for close monitoring of the patient was ensured. It has been reported that general anesthesia is partially responsible for periprocedural hypotension in more than 50% of patients [13], which could be due to the long intraprocedural duration ( $186.2 \pm 54.1$  min) and the negative impact of volatile anesthetics on vasomotor tone and myocardial contractility [22, 23]. An interesting finding of our study was the lack of necessary pharmacologic interventions.

Several previous studies reported on the use of midazolam for controlled sedation in CIED procedures. We demonstrated that the combination of midazolam with propofol for controlled sedation in this cohort of patients with reduced ejection fraction is possible, feasible, and safe. Even in obese patients with a BMI  $\geq 30$  kg/m<sup>2</sup>, the procedure was performed without hemodynamic or respiratory problems.

Using the intermuscular technique for surgical S-ICD implantation ensured safe and efficient healing of the incision site. We experienced no pocket complications, irrespective of the patients' body mass index, whereas previous studies using the conventional subcutaneous implantation technique showed high rates of pocket complications, ranging from 7.6 to 11.9% [11]. However, considering the retrospective analysis of only a small patient cohort group and the lack of an existing control group under general anesthesia it is not really possible to conclude that this approach is safe, despite the absence of perioperative complications in our cohort. Still, the results of our study can serve as a hypothesis generation for the potential safety of S-ICD implantation under conscious sedation.

It could be speculated if conscious sedation could result into shorter hospital stay by enhancing the rehabilitation process. To our knowledge, there are no specific data available evaluating types of anesthesia in device procedure with respect to the hospital stay. However, our analysis revealed a mean duration of 3.0 days, while the German pacemaker registry states a post-operative hospital stay of 4.7 days for de novo ICD implants, which would be lower than observed in our cohort. [24].

## 5 Limitations

The present study has several limitations. It is limited by its retrospective design, and a comparative analysis of local anesthesia with or without sedation was not performed. Further studies should also include randomized trials on local anesthesia with or without sedation. Furthermore, there is no specific hemodynamic data in detail beyond the regular interval documentation for the DFT testing period. Another limitation is the absence of a standardized approach to conscious sedation. Finally, we did not perform a detailed and standardized objective assessment of pain in prospective fashion using an established survey or questionnaire; but we asked the patients whether they felt any pain or discomfort after the procedure. Based on the low patient number and complication rates being only a secondary endpoint of our analysis, we cannot really state anything robust with respect to perioperative complications in this setting.

## 6 Conclusion

The use of S-ICD can be recommended for patients without pacing indications, in particular for patients with difficult venous anatomy, those who are younger, and those with prior infection due to transvenous devices. Little data is available on using different stages of sedation for the surgical implantation of S-ICDs rather than general anesthesia, which is used in the majority of cases. Our findings suggest that local anesthesia with conscious sedation using propofol and midazolam is a feasible option for S-ICD implantation procedures using the intermuscular technique, potentially offering good cosmetic results and improved incision healing for increased patient satisfaction.

## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethics approval and consent to participate** The study was approved by the ethics committee of the faculty of medicine of the University of Duisburg-Essen (Reference no. 17-7701-BO), Germany.

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