Subcutaneous implantable cardioverter-defibrillator (S-ICD) as an alternative, reliable heart rhythm sentinel – single center experience

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A - Research concept and design, B - Collection and/or assembly of data, C - Data analysis and interpretation, D - Writing the article, E - Critical revision of the article, F - Final approval of article

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Abstract

A subcutaneous implantable cardioverter-defibrillator (S-ICD) is an alternative for patients who require ICD implantation for sudden cardiac death prevention and who present contraindications for the traditional intravenous lead implantation, such as high risk of infection. Yet, this device is not without disadvantages, for example incapacity of heart pacing. In this paper we present a series of four patients, the first in our clinic who have been implanted with an S-ICD. Each of them presented with different indications for S-ICD implantation – increased risk of lead infection endocarditis and diabetes, increased risk of lead infection due to dialysis and catheter infection, anatomical impossibility to implant a transvenous ICD (T-ICD) and prevention of long-term T-ICD complications. The implantations were successful, and the patients are currently under follow-up. These cases show that the S-ICD device in a certain group of patients is a reasonable alternative, especially when pacing therapy is not necessary.

Key words:

subcutaneous implantable cardioverter-defibrillator (S-ICD), implantation, cardiac device related infective endocarditis, primary and secondary prevention.

Case descriptions

Case 1
A 61-year-old man with chronic heart failure and a cardiac resynchronization therapy defibrillator (CRT-D) device (implanted 6 months before the current admission) was transferred to the Independent Public Central Clinical Hospital in Warsaw (1st Department of Cardiology) from a local district hospital with the diagnosis of cardiac device related infective endocarditis. The patient was admitted with fever, leukocytosis (WBC 13.5x10^3 /mm^3) and high CRP (334 mg/l), whereas blood culture tests were positive for Gram-positive cocci. In transesophageal echocardiography vegetations attached to the lead were observed – therefore the diagnosis of cardiac device related infective endocarditis (CDRIE) was made. In addition, the patient manifested other comorbidities including diabetes mellitus with diabetic foot syndrome, persistent atrial fibrillation, coronary artery disease, and chronic renal failure (stage 3 according to KDIGO). Antibiotic therapy was introduced according to guidelines immediately after admission, whereas the infected CRT-D device was extracted after 4 weeks. Antibiotic therapy was continued after the extraction and vancomycin was ceased 6 weeks after the removal; control blood culture tests were negative. With transesophageal echocardiography performed after cessation of antibiotic therapy there were no signs of vegetation. With transthoracic echocardiography left ventricle ejection fraction was low: 30%. According to ESC and AHA guidelines, there were indications for implantable cardioverter-defibrillator (ICD) implantation. However, the risk of serious infection (including CDRIE) in the patient was high, so the patient was finally implanted with an S-ICD, instead of a T-ICD or CRT-D (Figure 1).

Figure 1. An S-ICD device.
The intervention was completed successfully. The device was implanted on the left anterior axillary line (Figure 2).

**Figure 2.** The intervention of S-ICD implantation.

There were no perioperative complications. A control chest X-ray was performed (Figure 3). Then the device was programmed and controlled. Eleven days after the S-ICD implantation the patient was discharged and instructed to attend regular control visits in the Implantable Cardiac Device Control and Telemonitoring Workshop, 1st Department of Cardiology.

**Figure 3.** First patient – X-ray examination – posteroanterior projection (A) and lateral projection (B).

**Case 2**

A 36-year-old man with a history of cardiac arrest (mechanism of ventricular fibrillation – February 2015) was transferred to our department from another university clinic after an unsuccessful trial to implant a T-ICD in secondary prevention of sudden cardiac death. The patient had a history of congestive heart failure in NYHA class II, pulmonary embolism (diagnosed during hospitalization in a previous university clinic), suspicion of congenital thrombophilia, sustained atrial fibrillation, state after atrial septal defect type II and incorrect superior vena cava confluence correction in childhood. In Holter-ECG a significant amount of ventricular extrasystole was observed, including nsVT. Due to the history of ventricular fibrillation there was an indication for ICD therapy. However, the subclavian vein turned out to be inaccessible because of high level of tortuosity. Therefore, the decision of S-ICD implantation was made. The intervention was successful, without early complications and X-ray examination revealed no significant changes. The device has been checked and programmed. The patient is currently under follow-up, without any complications.

**Case 3**

A 62-year-old man with a history of congestive heart failure, suspected for infective endocarditis, was transferred to our department from a local district hospital. In that hospital two episodes of cardiac arrest occurred in a mechanism of ventricular fibrillation (July 2015). In addition, the patient had a history of diabetes mellitus type 2, end-stage chronic kidney disease on dialysis therapy for 2 years (dialysis catheter in left jugular vein), anemia of chronic diseases, and the state after a few endovascular and surgical interventions upon peripheral arteries (PCI of left subclavian artery, femoral-popliteal vascular grafting, carotid endarterectomy). On admission, the patient presented fever and increased inflammatory markers (CRP 36 mg/l). Transesophageal echocardiography did not reveal any vegetations, so infective endocarditis was excluded. The inflammation did not resolve for two weeks despite antibiotic therapy with 2nd generation cephalosporin. After that time, the dialysis catheter and central venous catheter were removed and another blood culture test was performed. This blood culture test was positive for Klebsiella pneumoniae ESBL (+), so targeted antibiotic therapy with imipenem/cilastatin was introduced. The fever disappeared and inflammatory parameters decreased. A provisional dialysis catheter was implanted into the left femoral vein five days after previous catheter removal. After 3 weeks, when the infection had been treated and inflammatory parameters had been normalized, an S-ICD device was implanted. The control X-ray examination revealed no significant changes. The device has been checked and programmed. Currently, the patient is under follow-up.

**Case 4**

A 28-year-old woman with a history of mitral prolapse, ventricular arrhythmia and unexplained syncope in the past was admitted to hospital after cardiac arrest which was successfully reanimated with an AED device by witnesses in the...
patient’s workplace. The patient was initially admitted to the Neurology Department. Neurological investigations, including head CT, head MRI and CSF examination, were normal. Then the patient was transferred to the Cardiology Department. Cardiologic diagnostic procedures were introduced – ECG was normal, in Holter ECG only several ventricular extrasystolic beats were observed, coronary artery CT showed no changes in the arteries and heart MRI excluded signs of myocarditis. An electrophysiological investigation was undertaken and AV nodal reentrant tachycardia with a heart rate of 220/min was evoked and subjected to an ablation procedure. Although ventricular tachycardia was not induced during the electrophysiological examination, moderately numerous ventricular extrasystoles were observed. Finally, the patient was implanted with an S-ICD device, which was then controlled and programmed. The X-ray chest examination performed after the implantation was normal. The patient was discharged and submitted to ambulatory follow-up. In addition, she was referred for ambulatory neurological and cardiological care, with the perspective for ventricular extrasystole ablation in the future.

**Summary of cases**

All these patients are summarized in Table 1 (clinical characteristics) and Table 2 (procedural characteristics).

### Table 1. S-ICD implanted patients’ clinical characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
<th>Patient 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initials</td>
<td>K.O.</td>
<td>K.N.</td>
<td>J.M.</td>
<td>M.J.</td>
</tr>
<tr>
<td>Age</td>
<td>61</td>
<td>36</td>
<td>62</td>
<td>28</td>
</tr>
<tr>
<td>Sex</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>F</td>
</tr>
<tr>
<td>Indication for ICD (primary/secondary)</td>
<td>Primary</td>
<td>Secondary</td>
<td>Secondary</td>
<td>Secondary</td>
</tr>
<tr>
<td>Previous ICD explantation</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Cause of explantation</td>
<td>CDRIE</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Diabetes (diabetic foot syndrome), CAD, CKD 3 degree</td>
<td>Pulmonary embolism, state after ASD II correction</td>
<td>End stage chronic kidney disease (dialysis), diabetes, PAD</td>
<td>Ventricular arrhythmia, mitral prolapse, suspected epilepsy</td>
</tr>
<tr>
<td>Echocardiography LVEF</td>
<td>30%</td>
<td>N.D.</td>
<td>45%</td>
<td>48.3% (MRI)</td>
</tr>
</tbody>
</table>

### Table 2. S-ICD implanted patients’ clinical characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
<th>Patient 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful/unsuccessful</td>
<td>Successful</td>
<td>Successful</td>
<td>Successful</td>
<td>Successful</td>
</tr>
<tr>
<td>Fluoroscopy use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Procedure duration</td>
<td>2,5 hours</td>
<td>1,5 hours</td>
<td>2 hours</td>
<td>1,5 hours</td>
</tr>
<tr>
<td>Site of pocket</td>
<td>Intermuscular</td>
<td>Superficial</td>
<td>Superficial</td>
<td>Superficial</td>
</tr>
<tr>
<td>Complications</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Complications (details)</td>
<td>-</td>
<td>-</td>
<td>Local access site hematoma</td>
<td>-</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>Figure 3</td>
<td>Figure 4</td>
<td>Figure 5</td>
<td>Figure 6</td>
</tr>
<tr>
<td>DFT test (example of DFT test in Figure 7)</td>
<td>30%</td>
<td>N.D.</td>
<td>45%</td>
<td>48.3% (MRI)</td>
</tr>
</tbody>
</table>
Figure 3. First patient – X-ray examination – posteroanterior projection (A) and lateral projection (B).

Figure 4. Second patient – X-ray examination – posteroanterior projection (A) and lateral projection (B).

Figure 5. Third patient – X-ray examination – posteroanterior projection (A) and lateral projection (B).

Figure 6. Fourth patient – X-ray examination – posteroanterior projection (A) and lateral projection (B).

Figure 7. A sample DFT test undergone in the patients after S-ICD implantation.

Comments

Nowadays, the S-ICD device is hoped to be a real alternative for patients who have indications for ICD-implantation because of sudden cardiac death risk, but whose clinical condition makes traditional T-ICD implantation either risky or surgically impossible. One crucial condition is no necessity for pacing therapy\(^1\). It is necessary to emphasize that there are diverse clinical indications for S-ICD implantation, as was reflected in our series of patients. In the first patient with CDRIE, the CRT-D system was removed according to ESC guidelines\(^2\) and ICD implantation was indicated in primary sudden cardiac death prevention (congestive heart failure NYHA III with LVEF≤ 35\%)\(^3\). However, according to Ann HW et al.\(^4\), repeated procedures were independent risk factors for device-related infections in multivariate analysis.

An additional risk factor for the patient was diabetes with diabetic foot\(^5\). In addition, during the entire period of hospitalization, inflammatory parameter levels were increased (for instance CRP varied from 40 to 100 mg/dl, procalcitonin level was normal, CRP normalized at the end of hospitalization). Of note, the patient was under telemetric heart rate control, the mean heart rate was 80-90 beats/min (atrial fibrillation as basic rhythm) and there were no episodes of bradyarrhythmia.

It means that there were no indications for artificial pacing. Resynchronization therapy before old CRT-D extraction was ineffective in the patient with sustained atrial fibrillation, and CRT-D implantation following A-V node ablation was considered too risky because of the increased probability of further infections. Finally, due to increased infective risk in the first patient an S-ICD was implanted, instead of a T-ICD or CRT-D.

In the second patient T-ICD implantation was prohibited by venous network anatomy, so an S-ICD was implanted. Venous abnormalities are not rare among patients requiring
pacemaker or ICD therapy and can make transvenous implantation impossible to accomplish[6]. In the third patient there was a significant problem of dialysis. In order to avoid the risk of central vein occlusion (increased in case of T-ICD) which might affect the dialysis functionality, S-ICD implantation is considered to be a good alternative to traditional T-ICD implantation. Moreover, diabetes mellitus type 2, state after sepsis therapy and chronic kidney disease on dialysis catheter significantly increase the risk of infection in the future, which make S-ICD implantation a more reasonable choice[7,8]. During the observation period after the intervention, one minor complication occurred – local hematoma, which resolved after modification of anticoagulation therapy. Finally, in the fourth patient, a young woman requiring ICD implantation after modification of anticoagulation therapy. In this case, implanting a T-ICD due to long life expectancy. In this case, implanting a T-ICD with an endocardial lead system could put the patient at increased risk of serious systemic and potentially mortal complications such as CDRIE. The S-ICD device tends to be effective and presents low incidence of device-related complications (especially infective endocarditis)[9].

In conclusion, our first experience with S-ICD implantation indicates that this device is a reasonable and reliable alternative for patients who present contraindications for T-ICD implantation and do not require pacing therapy.

Acknowledgements

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Disclosures

None declared.