Gleneagles Hospital
HONG KONG
港怡醫院

Hosp No.	:	HKID No.:
Case No.	:	
Name	:	
DOB	:	M / F
Adm Date	:	
Contact No.	:	

Procedure Information Sheet – Subcutaneous Implantable Defibrillator

1. Introduction

1.1. Heart rhythm is mainly controlled by the conduction system of the heart. Any abnormality in the conduction system may result in abnormal heart rhythm (arrhythmia). Life-threatening arrhythmias such as ventricular tachycardia (VT) and ventricular fibrillation (VF) cause not only palpitations, dizziness and syncope but also sudden death. Subcutaneous Implantable Defibrillator (S-ICD) is an implantable device used for treatment of VT and VF. It is essentially an implantable defibrillator which consists of a battery-powered generator and an electrode which connects to the generator. As soon as a VT or VF is detected, the S-ICD will automatically try to correct it by defibrillation.

2. Importance of Procedure

2.1. It has been proven in various clinical trials that ICD (including S-ICD) is better than the best anti-arrhythmic drugs in prolonging survival among patients with a high risk of sudden cardiac death due to VT or VF. If you refuse this procedure, the result may be detrimental or even fatal. Alternative treatments include implantation of traditional ICD, anti-arrhythmic drugs and catheter ablation.

3. Before the Procedure

3.1. You may be required to have special tests such as electrophysiology study (EPS), or stop some or all of the anti-arrhythmic drugs before the procedure.
3.2. If you experience severe symptom during this period (e.g. palpitation or fainting attack), please seek immediate medical attendance at nearby clinic or Accident & Emergency Department.
3.3. You need to sign an informed consent.
3.4. You need to undergo investigations like blood tests, electrocardiogram and chest X-ray.
3.5. Blood thinning drugs may have to be stopped several days before the procedure.
3.6. An IV infusion will be set up and you need to fast for 4-6 hours.
3.7. Shaving near the implant site may be required.
3.8. If you are a female, please provide your last menstrual period (LMP) and avoid pregnancy before the procedure as this procedure involves exposure to radiation.

4. The Procedure

4.1. This invasive procedure is usually performed under general anesthesia or monitored anaesthesia care (MAC) in a cardiac catheterization centre.
4.2. Electrodes are adhered to the chest to monitor the heart rate and rhythm. Blood oxygen monitor through your finger tip will be set up. Measurement of blood pressure from your arm will be taken during the examination.
4.3. Skin disinfection will be performed and a small skin incision (about 6 cm long) will be made under your left side of rib cage.
4.4. Two small incisions are made close to the breastbone allowing placement of the subcutaneous electrode under the skin.
4.5. The generator will be connected with the electrode and implanted in a pocket created under the skin or muscle.
4.6. VF may be induced under sedation for testing the proper functioning of the S-ICD.
4.7. The wound will be closed with suturing material and covered with pressure dressing.
4.8. The procedure usually takes around 2 to 3 hours.

5. After the Procedure

5.1. After the procedure, you will be kept on close monitoring in the ward.
5.2. Nursing staff will check your pulse and wound regularly.
5.3. You should inform your nurse if you find blood oozing from the wound site.
5.4. You may resume oral diet as instructed.
5.5. Mild wound pain is common. You may take simple analgesic to relieve pain.

5.6. Antibiotics may be given for a few days to minimize the risk of wound infection.
5.7. Pre-discharge S-ICD testing and programming may be performed.
5.8. You may be discharged from hospital a few days after the S-ICD implantation.

6. Follow Up

6.1. The wound should be covered with light dressing. Please keep the wound site clean and avoid making the dressing wet during a bath. Always change dressing if wet.
6.2. Please avoid vigorous arm movement in the first month after the procedure.
6.3. You will be arranged to attend S-ICD clinic for regular S-ICD analysis, re-programming and battery power assessment.
6.4. Please carry your S-ICD identity card at all times.
6.5. Follow your doctor's instructions or refer to the information booklet from the S-ICD company to minimize the risk of pacemaker malfunction due to electromagnetic interference. In general, strong electro-magnetic field or radiofrequency signal will interfere your S-ICD. Please keep a distance of >15 cm (6 inches) from an active mobile phone. Household electrical or electronic appliance usually does not affect S-ICD.
6.6. You should report to your doctor or nearby Accident and Emergency Department if you suffer from syncope or electric shocks delivered by the S-ICD.
6.7. S-ICD generator will need to be replaced several years later when the battery is depleted.

7. Risks and Complications

7.1. The procedure carries certain risks.
7.2. Major complications include death (<1%).
7.3. Other potential risks include wound infection (<1%), wound haematoma (<1%),
7.4. Special risks related to the device include electrode dislodgement, insulation break or fracture, and pocket erosion.
7.5. Broken guidewire (0.1-0.8%).

8. Remarks

8.1. It is hard to mention all the possible consequences if this procedure is refused.
8.2. The list of complications is not exhaustive and other unforeseen complications may occasionally occur. The risk quoted is in general terms. In special patient group (e.g. diabetics), the actual risk may be higher.
8.3. Should a complication occur, another life-saving procedure or treatment may be required immediately.
8.4. If there is further query concerning this procedure, please feel free to contact your nurse or your doctor.

9. Reference

9.1. Association for European Pediatric and Congenital Cardiology (2015). 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death – European Heart Journal 2015; 36 (41): 2793-2867
9.2. Burke,M.C., Gold, M.R. Knight, B.P., et al. (2015). Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-year results from a Pooled Analysis of the IDE Study and EFFORTLESS Registry. Journal of the American College of Cardiology 2015; 46(16):1605-1615
9.3. Epstein, A.E., DiMarco, J.P., Ellenbogen, K.A., et al (2013). 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities. Circulation. 2013 Jan 22; 127(3):e283-352. Epub 2012 Dec 19.
9.4. Zipes, D.P., Cam, A.J., Borggreffe, M., et al. (2006). ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. J Am Coll Cardiol September 5, 2006:e247-e346.
9.5. Hospital Authority. Smart Patient Website.

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I acknowledged the above information concerning the operation or procedure. I have also been given the opportunity to ask questions and received adequate explanations concerning the condition and treatment plan.

Patient/ Relative Signature: _____

Patient/ Relative Name: _____

Date: _____