VALLEYCARE OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS ANGIOGRAPHY SUITE/CARDIOLOGY DIVISION POLICY & PROCEDURE PACEMAKER/AICD IMPLANTATION

NUMBER: 1891 VERSION: 1

SUBJECT/TITLE: AUTOMATIC IMPLANTABLE CARDIOVERTER - DEFIBRILLATOR (AICD) IMPLANTATION

POLICY: I. Definition of Service

AICD's are special devices, in appearance very similar to a permanent pacemaker. They were developed to aid in the management of potentially lethal arrhythmias. These arrhythmias have a high rate of recurrance, and therefore carry a poor prognosis for the patient. AICD's have been shown to prolong survival significantly in certain scenarios. The device is able to deliver cardioversion-defibrillation shocks through an internal lead. They are also able to pace if necessary. The device continuously monitors the patients heart rhythm and is programmed to deliver shocks or pacing at specified heart rates and rhythms.

A. Indications

- 1. History of cardiac arrest due to ventricular fibrillation or tachycardia not due to a transient or reversible cause.
- 2. History of spontaneous ventricular tachycardia
- 3. Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained ventricular tachycardia/ fibrillation induced at electrophysiology study.
- 4. Nonsustained ventricular tachycardia with underlying coronary artery disease and/or ventricular dysfunction with sustained ventricular tachycardia/fibrillation induced at EPS.
- 5. Patients at high risk for sudden death such as patients with familial cardiomyopathy, long QT syndrome, hypertrophic cardiomyopathy with family history of sudden cardiac death.
- 6. There are other indications in patients that fit between definitely indicated and not indicated. The clinician must use best judgment until more information via randomized trials is available.

 These consist of non-ischemic cardiomyopathy with

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syncope or non-ischemic cardiomyopathy with symptomatic non-sustained ventricular tachycardia.

B. Contraindications

- 1. Incessant ventricular tachycardia
- 2. Ventricular arrhythmias due to reversible causes
- 3. Special warning post implantation: Magnetic Resonance Imaging and lithotripsy if generator is in field are CONTRAINDICATED.

C. Risk of Procedure

- a. Operative mortality is <1%
- b. Infection of pulse generator or leads is approximately 2%
- c. Other possible complication risk is low and not life threatening, these include: Lead fracture or dislodgement, hemothorax, pneumothorax, hematoma of pulse generator pocket, and inappropriate delivery of therapy.

DEPARTMENTS: All

PROCEDURE: II. Definition of Procedure

A. Level of Personnel

Attending Cardiology Faculty member to implant device, AICD implant technician for programming and testing intra-operatively, personnel qualified to administer conscious sedation (anesthesiologist, nurse anesthetist, or R.N. with M.D. orders), personnel qualified to monitor the patient and circulate during the procedure (anesthesiologist, nurse anesthetist, or R.N.), radiology technician to operate fluoroscopy equipment.

B. Equipment/Medications

- 1. Equipment
 - a. Appropriate sterile environment in procedure room, this may be in an operating room or catheterization laboratory. Appropriate supplies for maintaining sterile procedure.
 - b. Fluoroscopy equipment
 - c. Equipment to monitor blood pressure, heart rhythm, oxygen saturation
 - d. Two "crash carts" available, at least one in the room. Both carts with tested, functioning external defibrillators.
 - e. Pulse generator (device) and implantable leads

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- f. Programmer to program and test device
- g. 12-lead EKG machine available

2. Medications

- a. Pre-operative antibiotics
- b. Topical injectable anesthesia
- c. Various agents for conscious sedation at the discretion of the Attending Cardiologist, Anesthesiologist, or Nurse Anesthetist
- d. Medications found in standard crash cart

C. General Considerations

- 1. AICD implantation is performed on inpatients. Pulse generator change can be performed on an outpatient basis.
- 2. Patients will require a monitored bed for at least 24 hours post implantation of a new device.
- 3. The Cardiology Service will determine the level of inpatient care required on an individual basis.

D. Pre-Procedure

- 1. Pre-procedure patient instructions will be given by a physician or nurse knowledgeable in the procedure.
- 2. Consent will be obtained by a physician.
- 3. Patient will be NPO from midnight of evening prior to procedure, except in extreme circumstances.
- 4. Prophylactic antibiotics will be administered prior to the procedure.
- 5. Before the start of the procedure a "Time Out Process" will be completed. Elements of the "Time Out Process" will include: verification patient identification, procedure to be performed, correct side and site, correct position, all equipment/supplies/ implants required for case in room ready and accessible, patient consent signature matches patient hospital medical identification and other special considerations. This will also include: NPO status, and readiness of resuscitation equipment.

E. During the Procedure

1. Patient will be monitored with automatic blood pressure cuff or intra-arterial line as appropriate, continuous ECG monitor, and pulse oximetry. Monitoring of vital signs, O2, ECG rhythm, and general well-being will be continuous, and documented. The Attending Cardiologist will be

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immediately alerted to any abnormality or potential abnormality; particularly hypotension, respiratory depression, O2 desaturation, arrhythmia.

- 2. Intravenous anesthesia, conscious sedation, will be administered by M.D., R.N. with M.D. order, or nurse anesthetist.
- 3. The Cardiologist will implant the device. This consists of pocket construction above the pectoral fascia plane for the pulse generator and implanting the leads via the subclavian vein to the right ventricle and right atrium with fluoroscopic guidance. This is done in the standard fashion for permanent pacemakers. After the device is implanted and the leads tested, further testing will be carried out. This consists of testing the defibrillation threshold of the device. Ventricular tachycardia or fibrillation will be induced and terminated by the device. In case of device malfunction, two external defibrillators will be on standby.

F. Post Procedure

- 1. After full testing and programming of the device, the patient will be observed in the recovery area. This will be done as per Conscious Sedation Protocol with monitoring of vital signs etc. and utilizing the Aldrete Score.
- 2. When the patient is fully recovered and appropriate for transfer, he/she will be taken to a monitored bed.
- 3. Patient instructions: wound care of incision site, cannot lift arm on side of device insertion above the level of the shoulder for 2 weeks. Follow-up will be scheduled in the Pacemaker Clinic.

III Quality Assessment

A. Infection Control

Universal infection precautions are to be observed.

A. Procedure Complications

All procedures, complications, and statistical data will be maintained and reviewed periodically.

A. Staff Qualifications and Privileging

The Attending Cardiologist must have Hospital Staff Privileges in good standing. These will consist of either Pacemaker implantation and Electrophysiology Studies, Pacemaker implantation with special competence for AICD testing, or AICD implantation.

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Documentation of proctoring and competence is required.

| References: 2008 AORN Standards and Recommended Practices | |
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