Same Day Subcutaneous ICD And Send Home

(DASH)

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Protocol Summary

Title: Same Day Discharge Protocol for patients undergoing Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

Design: Prospective, non-randomized single center study at The Ohio State University Wexner Medical Center.

Purpose: The purpose of this study is to prospectively evaluate a specific analgesia protocol designed to allow for same day discharge following implantation of the S-ICD.

Enrollment: Up to 50 subjects will be enrolled.

Subject Population: Consecutive patients undergoing S-ICD implantation under general anesthesia or monitored anesthesia care.

Endpoints: Rate of successful completion of the protocol; Procedural complications; Serial assessment of patient perception of pain.

BACKGROUND

The number of subcutaneous implantable cardioverter-defibrillators (S-ICD) being implanted is steadily increasing; however, an important limitation to adoption of this technology is the perception for the need to admit patients overnight for pain management after device implantation.[1] Furthermore, there is a great interest to perform more procedures in an outpatient setting so to reduce resource utilization and to minimize use of inpatient beds potentially available for other patients. To date, there are no published studies regarding a protocol for outpatient management of patients undergoing implantation of S-ICD. At the Ohio State University Medical Center, we have implemented an institutional protocol to allow same-day discharge following S-ICD implantation, and S-ICD implantation is currently performed on an outpatient basis. The purpose, therefore, of this protocol is to complete a prospective evaluation of an outpatient analgesia protocol in consecutive patients undergoing S-ICD implantation.

STUDY OBJECTIVES AND ENDPOINTS

Objectives

To prospectively evaluate the same day discharge protocol for patients undergoing S-ICD implantation.

Primary Endpoint

1. Rate of successful completion of S-ICD implantation and discharge of the patient on the same day the device is implanted using the analgesia protocol.

Secondary Endpoints

1. Procedure complication (failed implantation, infection, hematoma/bleeding, etc…) within 30 days of procedure.
2. Serial assessment of patient perception of pain using the graded integer pain scale of 0-10
3. Side effects related to medical therapy of protocol.
4. Time from beginning of recovery (defined as when the patient enters the recovery room) to the time of discharge from the recovery unit.
5. 30 day readmission rate after discharge following S-ICD implant
6. Number of days that oral analgesics are used post discharge.

STATISTICAL ANALYSIS

The primary endpoint is rate of successful completion of device implantation and discharge of the patient on the same day that the S-ICD device is implanted. The estimated success of the protocol is ≥85%.

Although it is anticipated that the patient will be discharged about 3 hours post procedure, if the patient requires a longer period of time but then is discharged on the same day, this outcome would be considered a successful completion of the protocol. Time from entry into the recovery area to the time of discharge will be collected. Patients who are enrolled in the study and begin the protocol but then transition to being admitted overnight will be considered a failed protocol, even if the patient is discharged within 24 hours of the

procedure. The enrollment rate is expected to be 2 -3 patients per month for 18 months, with enrollment completed at the Ohio State University Wexner Medical Center (OSUWMC).

In addition to the data collated to complete the primary and secondary endpoints, other data to be collected by the dedicated electrophysiology research nurse and anesthesia technician include: age, gender, body mass index, creatinine, etiology of cardiac disease, indication for S-ICD therapy (primary vs secondary prevention), episode of sustained ventricular tachycardia, episode of sudden cardiac arrest, New York Heart Association (NYHA) Heart Failure Classification, left ventricular ejection fraction, the American Society of Anesthesiologists (ASA) classification, Mallampati score, presence of other comorbidities (valvular disease and if so which type, presence of congenital heart disease and if so which type, sleep apnea, pulmonary hypertension, chronic obstructive pulmonary disease, requirement for oxygen supplementation, chronic kidney disease, Eisenmenger's syndrome, atrial fibrillation/flutter, diabetes, hypertension, stroke, liver disease), and ambulatory medical therapy (beta blockers, calcium channel blockers, ACEI or ARBs, antiplatelet, anticoagulants and use of Class I, III antiarrhythmics or amiodarone, and pain medications).

Intraoperative parameters to be collated are vital signs, oxygenation and carbon dioxide every 5 minutes from prior to induction until the patient leaves the implantation / electrophysiology laboratory following extubation, and duration of intubation. Anesthestic parameters to be recorded are methods of induction, type and doses of inhaled and intravensous anesthetics and analgesics, as well as dose and type of local anesthetic. The number of defibrillation testing and energy utilized will also be recorded.

STUDY DESIGN

This is a prospective, nonrandomized, descriptive, single center study designed to assess the rate of successful completion of the study protocol in consecutive patients undergoing S-ICD implantation.

Inclusion Criteria

- Patient consented for implantation of S-ICD.
- Ambulatory/outpatient patient coming to the hospital setting solely for implantation of S-ICD
- Patient agrees to participate and is able to comply with the defined study protocol, including assistance for home care and transportation for the first ≈12-18 hours post discharge, and compliance with the required follow up.

Exclusion Criteria

- Inability or unwillingness to provide informed consent
- Patients who, for any reason, was hospitalized or in an emergency department the day prior to the S-ICD implantation, including patients transferred for S-ICD implantation
- Patients in which the hemodynamics are dependent upon intravenous pressors infusing at the time of device implantation or mechanical support, inclusive of left ventricular assist device and intravenous devices (balloon pump, Impella device).
- Age < 18 years.
- Pregnancy.

- Currently incarcerated.
- Hypoxia (room air oxygen <91%) or acutely short of breath
- Hypotension (Systolic blood pressure <90) unless this is patient's typical blood pressure)
- Bradycardia (heart rate <45bpm, unless this is patient's typical resting heart rate)
- Acute electrolyte disorder that cannot be easily corrected (e.g., potassium supplementations) based upon Chem 6 values obtained on day of procedure
- Presence of a fever

STUDY PROTOCOL

Patient Identification & Consent

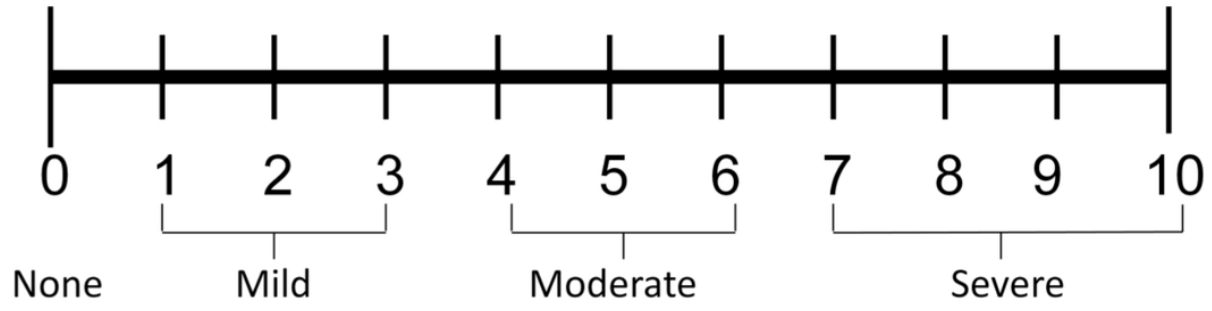
Patients will be approached for participation in the study once they have been consented for implantation of the clinically indicated S-ICD. Patients will be approached for participation by members of the electrophysiology staff, electrophysiology research team or by the anesthesiology team. The protocol will be reviewed with the patient and if agreed, the patient will sign consent and begin the protocol before initiation of therapy for the S-ICD implantation. As clinically indicated, a transthoracic echocardiogram or cardiac MRI will be reviewed for each patient.

Study Protocol

A multi-modal approach to analgesia is needed for timely discharge of patients after S-ICD implantation. The main criteria for discharge will be a combination of hemodynamic stability and adequate analgesia in the post-implantation period.

Assessment of Pain

Pain assessment will be completed at defined points of care using the peer-reviewed pain perception scoring system, the 0-10 Numerical Pain Rating Scale (NPRS).[2] The NPRS grades pain on a scale of 1 to10. A pain score of 1 equates to mild pain, a pain score of 5 equates to moderate pain, and a pain score of 10 equates to severe pain score.[2] Notably, the NPRS pain scoring system has been adopted for the assessment of pain after surgery at Ohio State University. The pain perception tool is provided below:



The Pain Perception Assessment questionnaire will be completed:

1. Baseline – defined as completion of the pain perception scale on a day prior to the procedure or on the day of the procedure but before placement of an intravenous catheter.
2. Within 1-2 hours post procedure while the patient is in recovery area.
3. 1 day post implantation (phone call)
4. 3 days post implantation (phone call)
5. 2 weeks post implant (phone call)

6. At 30 days post implantation (in-person device check) at OSU device clinic

Pre-Procedure

Patients will arrive to the pre-/ post- procedure preparation and recovery area ("IPR unit") about 2 hours prior to the start of the S-ICD implantation procedure. The nursing staff will inquire if the patient has arranged for appropriate transportation home or to a hotel room and if there is a person who will be with the patient for about the first 12-18 hours post procedure. If these parameters are not met and cannot be arranged before discharge, then the patient will not complete the study protocol and will be deemed a primary endpoint failure.

If not already compliant with hospital policy, a history and physical will be completed by the electrophysiology and anesthesia team as well as laboratory work (CBC, Chem 6 and INR). A peripheral IV will be placed. IV antibiotics in accordance with hospital protocol and to avoid allergic reaction will be administered.

<u>Pre-procedure analgesia</u> will be given to each patient as follows:

1. Acetaminophen 975 mg PO x 1 will be administered 1-2 hours prior to the procedure.
2. Oxycodone 10 mg PO x 1 will be administered 1-2 hours prior to the procedure.

Intra-Procedure

The patient will undergo device implantation in one of the approved electrophysiology laboratory procedure rooms. The choice of anesthetic will be at the discretion of the

attending anesthesiologist: monitored anesthesia care versus general anesthesia care.[1,4,5,6] Typically vital signs, airway assessment and oxygenation/carbon dioxide will be monitored and documented every 5 minutes.[4,5] The left chest, axilla, subxyphoid and sternal regions will be prepped and draped in usual sterile manner. The customary implantation technique will be the 2-incision approach followed by defibrillation testing at 65J.[4,5] The goal is to have the S-ICD generator placed posteriorly in intimate contact with muscle along the chest wall and for the electrode to be directed vertically left of the left sternal border. The specific device implantation technique, however, will be at the discretion of the electrophysiologist to achieve optimal outcomes. Fluoroscopy will be available and can be utilized at the discretion of the electrophysiologist.

Local Anesthesia: The ideal local anesthetic for S-ICD implantation is yet to be determined. Most clinicians use 1% lidocaine with has a very rapid onset but a very short duration of action, and offers minimal post-procedure analgesia. Bupivacaine is a very long-acting local anesthetic which will provide significant post-implantation analgesia (6-8 hours); however, due its delayed onset of action of ~ 15 minutes, bupivacaine has not been adopted by most electrophysiologists.[7,8,9] A combination of lidocaine and bupivacaine may be the best local anesthetic solution for S-ICD implantation to ensure rapid onset of anesthesia and prolonged analgesia.[8,9] This combination of local anesthetics (lidocaine/bupivacaine solution) has a proven efficacy and safety margin.[8,9]

- Create a 50:50 mixture of 2% lidocaine and 0.5% bupivacaine; which will result in a concentration of 1% lidocaine and 0.25% bupivacaine.[8,9] Administer 2.5 mg/kg (equivalent to 1 ml/kg) of the 50:50 solution of 2%

lidocaine and 0.5% bupivacaine for a field block at the pulse generator can and the parasternal lead tunneling sites. Considering that the maximum allowed dose of lidocaine is 4.5 mg/kg whereas the maximum allowed dose of bupivacaine is 3 mg/kg, the study patients will be dosed with 2.5 mg/kg which will allow a safety margin of 0.5 mg/kg for bupivacaine and 2.0 mg/kg for lidocaine.[7]

Post-Procedure

Patients will recover in IPR. Both the electrophysiologist and the anesthesiologist will assess patients for hemodynamic stability and adequate analgesia (pain score less than 5 or return to preoperative pain level in patients with chronic pain) before discharge. Vital signs will be documented approximately every 15 min x 4, every 30 minutes x 2 then, if no complications, prepare for discharge. In the IPR, choice of medications for pain control will be at the discretion of the attending anesthesiologist.

Preparing for Discharge

Starting at ≈2 hours post procedure, the patient will then enter the "Preparation for Discharge" phase. The modified Aldrete scoring system will be used to determine eligibility for discharge home.[10] Patients with an Aldrete score ≥ 9 (score system described below) will be deemed eligible for discharge home.

Aldrete Scoring with SpO_2 System			
Category	Description of Status	Score	Comments
Activity	Moves 4 extremities voluntarily or on command Moves 2 extremities voluntarily or on command Moves 0 extremities voluntarily or on command	2 1 0	Movement of all four extremities either spontaneously or upon command in presence of pre-existing condition which would preclude the evaluation of these requirements.
Respiration	Able to breathe and cough freely Dyspnea or limited breathing Apneic	2 1 0	The patient must maintain an O_2 sat $\geq$ 92%, either on room air or prescribed O_2 therapy for the floor unless patient's baseline dictates otherwise.
Circulation	BP within 20% of preanesthetic level BP within 20-50% of preanesthetic level BP within 50% of preanesthetic level	2 1 0	The patient's vital signs have been stable for 30 minutes, being within 20% of preanesthetic vital signs. Blood pressure does not deviate more than 20% from pre-anesthetic readings.
Consciousness	Fully awake Arousable on calling Not responding	2 1 0	The patient is awake or easily arousable and responsive to verbal stimuli in presence of pre-existing condition, which would preclude the evaluation of these requirements. Patients who were alert pre-operatively should be oriented to person, place and time at discharge
O_2 Saturation	Able to maintain SaO_2 above 92% on room air Needs O_2 to maintain SaO_2 above 90% SaO_2 below 90% even with O_2	2 1 0	The patient has regained all protective reflexes necessary to maintain a clear airway, i.e., cough reflex, gag reflex. The patient must have respirations 8 or greater.

Additional standard ambulatory discharge criteria per the OSUWMC postanesthesia care policy statement will be applied by the nursing team, akin to all ambulatory surgery patients at OSUWMC. If the above discharge parameters (DP) are not meet, the patient will be reassessed every 30 minutes until parameters are satisfied. Once the patient satisfies the DP, the patient will complete the Pain Perception Questionnaire and be assessed for ambulation, eating/drinking and for understanding of post discharge instructions. The electrophysiology device nursing staff will review management of the S-ICD incision, device and post discharge care instructions with the patient and with the accompanying family member(s)/friend. The patient will be given instructions regarding management of pain and will be provided the following prescription for outpatient pain control:

1. Percocet 5mg/325 mg (1 tablet every 6 hours). A 2-day supply will be given.

Also, the patient will be provided a phone number to contact during business hours as well as for after hours to address questions/concerns.

Post Discharge Care

The electrophysiology lab and device clinic nursing staff will contact the patient the following day, 3 days post discharge, and 14 days post discharge to administer the Pain Perception Questionnaire as well as to ask whether they have sought medical attention in the interim. The last Pain Perception questionnaire will be obtained at about 30 days post implantation during in-person device check at OSUMC device clinic.

Study Risks

Patients will receive the same care before, during, and after S-ICD implantation, including follow-up phone calls, regardless of whether they take part in this study. Therefore, there is no additional risk unique to this study beyond standard S-ICD implantation. At our OSUMC, S-ICD implantations are already routinely performed on an outpatient basis without mandatory overnight hospitalization. Same-day discharge patients are managed for pain control as an outpatient in a similar manner as an inpatient. Additionally, the hemodynamic parameters and the Aldrete score ≥ 9 are demonstrated to result in safe discharge of patients undergoing surgical procedures at OSUMC.

The study protocol will be stopped early if: (1) the rehospitalization rate within 30 days of the procedure is >15%; **and,** (2) rehospitalization is deemed to be related to a complication from the S-ICD procedure attributable to being discharged on the same day of device

implantation and a complication that would have been avoided by having the patient remain in the hospital one night post device implantation.

Publications

The goal of this study is to produce 2 manuscripts. One manuscript will focus upon the same day discharge protocol and will be submitted to an electrophysiology journal. The second manuscript will focus upon the anesthesia aspects of care with data stratified by type of anesthesia (general vs monitored anesthesia care), and this manuscript will be submitted to an anesthesia journal.

References

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