European Snap Shot Survey

On

Procedural Routines for Electronic Device Implants (ESSS-PREDI)

Study Protocol

Coordinating centre:

Scientific Initiatives Committee (SIC) of the
European Heart Rhythm Association (EHRA),
European Society of Cardiology (ESC)
2035 Route des Colles - Les Templiers, BP 179
06903 Sophia Antipolis - France

INTRODUCTION

About 1.25 million pacemakers and 410,000 implantable cardiac defibrillators (ICDs) are implanted worldwide, each year (1).

After Cardiac implantable electronic device (CIED) implantation, hematomas are not uncommon (2.9–9.5% of the cases)(2). They can be managed either conservatively or surgically. Evacuation is required in 0.3–2% of implants and is associated with a 15-fold increase in the risk of infection (3-6). Many hematomas can be avoided by careful haemostasis and preparation of the patient. Of paramount importance is the correct management of antiplatelet and anticoagulant drugs.

Up to 45% (3) of the subjects receiving a CIED may be indicated for oral anticoagulants and some of these subjects receive concomitant antiplatelet therapy (7,8).

Practice may vary a lot, ranging from no change in the anticoagulation regimen to interruption with or without bridging therapy. However, the use of heparin bridging to oral anticoagulation has been shown to increase the risk of bleeding and continuation of warfarin (INR <2.0) has been proposed by several authors (9,10). Recently, a large randomized study (11) confirmed the superiority of Warfarin continuation (with an actual median INR of 2.3) over heparin bridging. This new data will probably lead to a more homogeneous attitude regarding VKA anticoagulation. Few data are available regarding perioperative management of patients taking novel oral anticoagulants (thrombin or factor Xa inhibitors). Given the paucity of data available assessing procedure related bleeding complications around the time of cardiac device implantation, it is not recommended to continue these medications at the time of cardiac device implantation (13). Currently, it seems that the more common attitude is to withdraw NOACs as recommended for surgery and restart 24-48 hours after implantation. In patients needing continuous anticoagulation, bridging with LMWH is performed. However, due to the relative novelty of their use, physicians may have varying policies regarding the management of the drug during the perioperative period. The aim of the present snapshot registry is to get data from “real word” clinical practice in order to investigate how physicians manage the perioperative anticoagulation with oral anticoagulants and antiplatelet agents and to end-up with information regarding the factors that may be associated with bleeding/thrombotic complications and may warrant caution in the peri-operative period.

SNAPSHOT SURVEY OBJECTIVES

- The primary objective of the study is to describe the incidence of clinically significant acute (in-hospital) and sub-acute (before the 1st post-implant visit) pocket hematomas after CIED implantation in subjects taking anticoagulants and/or antiplatelet agents.

- The secondary objectives of the study are to:

Describe the incidence of hemorrhagic complications after CIED implantation in subjects taking anticoagulants and/or antiplatelet agents.

Describe the practice of antithrombotic management in the perioperative period (i.e. discontinuation or not before the procedure, bridging therapy or not, and continuation or not of the treatment after the procedure)

Identify predictors of clinically significant pocket hematoma : the following potential predictors of clinically significant pocket hematoma will be assessed : perioperative management of antithrombotic agents, type of procedure and implant, preventive measures of hematoma, local hemostasis measures, concomitant antiplatelet therapy, baseline characteristics, comorbidities and risks scores (CHA_2DS_2VASc and HASBLED scores, implantation type, selected comorbidities).

The complications will be captured either during the 1st post-implant scheduled visit (e.g. until 2 to 12weeks after implantation) or during any unscheduled visit related to bleeding complication. Physicians will enter at that time the informations related to the peri-procedural period.

SNAPSHOT SURVEY DESIGN:

In order to stick with snapshot survey requirements, data will be collected during one visit for each patient:

- the first post implant scheduled visit (generally after 2 to 12 weeks post implant)
  or
- any unscheduled visit motivated by a bleeding complication

Important note: In order to know how many patients were operated for CIED in each center during the study period, a log will be available at each center. The difference between the number of patients operated and the number of patients actually entered in the survey will give an idea of the completeness of the data.

PATIENTS:

Eligibility:

All consecutive subjects treated with antithrombotic agents (i.e. vitamin K antagonists, direct oral anticoagulants, antiplatelet agents) and receiving a CIED.

Inclusion criteria:

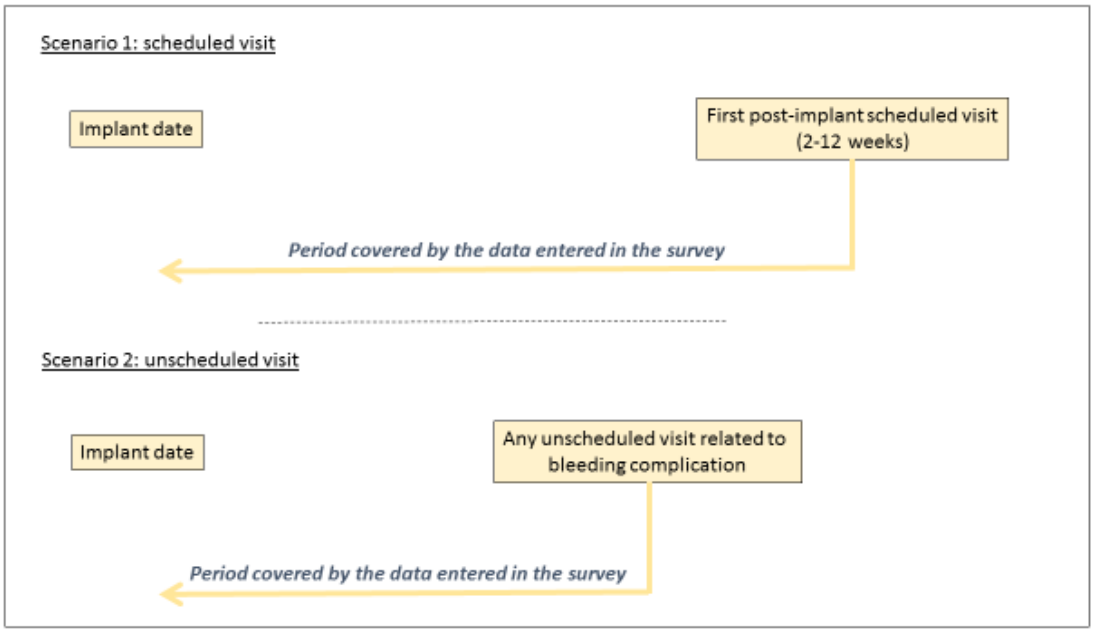
Subjects must meet the following criteria to be enrolled in the study:

- Male or female ≥ 18 years old
- Informed consent
- Treatment with antithrombotic agents
- Any CIED-related procedure (either first implant, generator or lead replacement, pocket revision)

Exclusion criteria :

- eligible patients who refuse to be part of the survey

DESIGN:



STATISTICAL AND ANALYTICAL PLANS :

Demographic and baseline characteristics of study subjects will be described by their number and percentage, when qualitative, and by their mean, median, standard deviation, minimum and maximum value, when continuous.

Incidence of acute and sub-acute pocket hematoma will be calculated as the number of pocket hematomas divided by the total number of subjects receiving CIED procedure and treated with anticoagulants/antiplatelet agents. The 95% confidence intervals will be estimated using the classical Normal approximation if appropriate, or the Poisson approximation in other case.

For the secondary objectives, the assessment of the association between the candidate variables and the occurrence of pocket hematoma will be investigated using non parametric tests in univariate analysis (Fisher exact probability, when qualitative, and U Mann-Whitney, when continuous). If the data allow, regression logistic model will be used to identify independent predictors.

All tests will be two-sided, and a P-value < 0.05 will be considered as significant. Statistical analysis will be performed using R software for Windows (version 3.0 or later).

Definitions :

A pocket hematoma *is defined as a palpable mass that protrudes ≥ 2 cm anterior to pulse generator (2). Pocket hematoma is evacuated on decision of the attending physician, in general in case of tense swelling with poor capillary perfusion, progressive enlargement, or severe pain to the patient. Blood transfusion is decided by the attending physician in case of severe anemia and/or poor tolerance of the anemia*

"Clinically significant pocket hematomas" are defined as follows:

- *Severe hematomas: if it warrants prolongation of hospitalization or re-hospitalization but no intervention*
- *Very severe hematomas: if it needs re-intervention and/or blood transfusion.*
- *Minor: if it does not warrant any additional therapy than careful follow-up*
- *Moderate: if it warrants pressure dressing for a prolonged period as compared to local clinical practice, and additional follow-up*

Definition of hemorrhagic complications:

GUSTO bleeding criteria :

- *Severe or life-threatening :*
  Intracerebral hemorrhage
  Resulting in substantial hemodynamic compromise requiring treatment
- *Moderate :*
  Requiring blood transfusion but not resulting in hemodynamic compromise
- *Mild*
  Bleeding that does not meet above criteria

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