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Same-day CIED implantation and discharge: is it possible? The E-MOTION trial (Early MObilization after cardiac implantable electronic device implantaTION)

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INTRODUCTION

Despite large variations between and within countries, the number of cardiac implantable electronic devices (CIED) procedures is constantly increasing worldwide[1–3]. The most common complication following CIED surgery is lead displacement ranging from 1.5%-5.5% occasionally requiring surgical re-intervention[4,5]. Poor lead stability induced by early post-operative mobilization is perceived as one of the strongest risk factors for lead dislodgement and most implanting centers prescribe strict bed rest for at least 24-hours to prevent this complication. However, there is paucity of data in support of this recommendation and the association between early mobilization and the occurrence of pacing lead (PL) dislodgement have been poorly investigated in recent years. In addition, prolonged immobilization following CIED surgery may prolong recovery, induce pain, reduce joint mobility and it may be difficult to implement especially in elderly patients[6–9]. Therefore, in the present real-world study, we sought to investigate the feasibility and clinical implications of early mobilization following CIED implantation. Specifically, we randomized patients undergoing CIED surgery to early (3-hours) mobilization with an arm sling (E-motion group [EMG]) or to standard (24-hours) immobilization (control group [CG]) comparing the occurrence of PL dislodgement and other procedure-related complications between the two groups.

METHODS

Study design

The Early MObilization after pacemaker implantaTION (EMOTION) trial was a prospective, randomized, investigator-initiated study. Patients undergoing CIED procedure between January 2014 and December 2015 were consecutively randomized in equal proportion to early (3-hours) mobilization with an arm sling (E-motion group [EMG]) or to standard (24-hours) immobilization (control group [CG]) following surgery.

The study was designed to have a statistical power of 80 percent based on a one-sided test, assuming an overall complication rate of 4 percent in the standard-mobilisation group, 16 percent in the early-mobilisation group, and enrollment of 200 patients (100 patients per arm).

The primary end-point of the trial was the occurrence of PL dislodgement. Secondary (safety) end-

point was the occurrence of any major intra-procedural complication (cardiac perforation, pericardial tamponade, valve damage, haemothorax, pneumothorax, myocardial infarction, peripheral embolus, TIA/stroke or death).

Patient population

This study included adult patients (>18 years old) with indication to CIED implantation according to contemporary guidelines[10,11]. Exclusion criteria were: CIED replacement or upgrading, cardiac resynchronization therapy device implantation, disabling conditions causing physical and mobility impairment (e.g. severe muscular dystrophies, spinal cord lesions).

The trial complied with the Declaration of Helsinki and subsequent modifications. All patients accepting to be enrolled in the trial gave oral and written informed consent.

Treatment protocol

Patients randomized to standard immobilization were recommended to observe strict bed rest for at least 24 hours after CIED procedure whereas patients randomized to early mobilization protocol were allowed to walk after three hours from surgery with the support of a Gilchrist bandage applied for 24 hours on the shoulder homolateral to device implantation (Figure 1). The experimental group was prudentially treated with the support of Gilchrist bandage and not allowed to free mobilization without any support because of the lack of previously reported experience in literature about early mobilization without any constriction. Regardless of randomization group, patients were instructed not to lift the arm homolateral to device implantation above shoulder level. In addition, pressure dressing of the pocket was applied for 3 hours after intervention in all patients on anticoagulant therapy at the time of CIED procedure.

Surgery was performed in accordance with current standards for CIED procedure, with atrial PL positioned in right atrial appendage and ventricular PL in right ventricular apex. Cephalic vein cut-down technique was used for PL insertion, or subclavian vein puncture as second choice. All interventions were performed from an experienced electrophysiologist (C.B.), with >170 procedures/year.

Device type (single vs. dual chamber, rate responsive vs. fixed rate) and PL (passive vs. active fixation, single vs. dual coil) were chosen in accordance to contemporary guidelines and patient's

clinical features. Chest X-ray was performed 24 hours after implantation using postero-anterior and lateral views to assess potential PL dislodgement, pneumothorax or haemotorax. Careful examination of surgical wound and device pocket as well as CIED test were performed after the intervention and before hospital discharge. Pocket haematomas, defined as a palpable swelling of the pocket, were categorized into 3 groups: mild (defined as ecchymosis or mild effusion, in the absence of swelling or pain); moderate (defined as moderate effusion causing pain or functional impairment or swelling); severe (defined, according to literature[10], as large effusion requiring oral anticoaugulation interruption or reoperation and/or resulting in prolongation of the index hospitalization).

Routine ambulatory follow-up was performed at one week, one month, three months, six months after the implantation. Annual and semi-annual follow-up visits were thereafter scheduled for pacemaker and ICD respectively.

All complications occurring within 24 months after CIED procedure were recorded and described along with possible invasive treatments (e.g. PL repositioning).

Statistical Analysis

Continuous variables, presented as means and standard deviations, were compared by non-parametric tests: Mann-Whitney's test was used for independent data and Wilcoxon's signed-rank test for paired data (pre-post evaluations). Categorical variables, presented as counts and percentages, were compared using the chi-square test with Yates' correction or Fisher's exact test: the risk ratio (RR) was computed with its 95% confidence interval (CI). All analyses were performed using the SPSS for Windows version 18.0 (SPSS, Inc., Chicago, Illinois) and a two-sided significance level of ≤0.05 was considered statistically significant. The survival probability and freedom from adverse events were evaluated with the Kaplan-Meier curves compared by the Mantel-Cox test.

RESULTS

Overall 200 patients were enrolled in the study and subsequently randomized to early (3-hours) mobilization with an arm sling (E-motion group [EMG], n=100) or to standard (24-hours) immobilization (control group [CG], n=100). Demographic and clinical characteristics were balanced

without significant differences between the two groups as detailed in Table I.

The majority (n=172, 86%) of patients included in the study underwent pacemaker implantation: 49 (28.5%) received a single-chamber device (25 in EMG vs. 24 in CG, p=0.92) whereas 123 (71.5%) received a dual-chamber device (60 in EMG vs. 63 in CG, p=0.77. The remaining 28 (14%) patients underwent an ICD implantation: 21 received a single-chamber device (11 in EMG vs. 10 in CG, p=0.99) whereas 7 a dual chamber device (4 in EMG vs. 3 in CG, p=0.99). Atrial PL fixation was passive in the vast majority of cases (n=126, 97%) without significant differences between EMG and CG (p=0.99). In 176 (88%) patients passive ventricular PL fixation was used without significant differences between groups (p=0.99).

Intra- and post-procedural complications

The overall incidence of PL dislodgement was comparable in both groups (3 in EMG vs. 4 in control group, p=0.99), as described in Table II and in Kaplan-Meier curves (Figure 2). Similarly, there were no differences in atrial (1 in EMG vs. 3 in CG respectively, p=0.62) or ventricular (2 in EMG vs. 1 in CG respectively, p=0.99) lead dislodgements overall. In addition, the number of surgical revision for lead displacement did not differ significantly in EMG vs. CG (3 in EMG vs. 2 in CG, p=0.99).

An early re-intervention was needed in 1 EMG patient because of inappropriate ICD shocks due to ventricular PL dislodgement and in 1 CG patient because of a complete atrial PL loss-of-capture due to a PL loop; both these complications occurred within 24 hours after CIED procedure. Remarkably, all other PL dislodgements were observed during the follow-up (late dislodgements): 3 atrial PL dislodgements (two in CG and one in EMG) were diagnosed after a median of 19 days [14-23] (one of which required a second intervention for repositioning), while 2 ventricular PL dislodgements (one in EMG and one in CG) were diagnosed respectively after 40 and 107 days (both required a second intervention for correct repositioning).

No major intra-procedural complications (i.e. cardiac perforation, pericardial tamponade, valve damage, haemothorax, pneumothorax, myocardial infarction, peripheral embolus, TIA/stroke or death) occurred. During a 24-month follow-up, PL dislodgement was observed in 7 patients (3.5%) in the overall population.

Drugs increasing bleeding risk

No baseline differences were observed between EMG and CG as to peri-procedural treatment with drugs increasing bleeding risk (such as oral anticoagulants, parenteral anticoagulants or antiplatelet agents), as shown in Table IIIA.

Pocket haematoma occurred in 14 patients (7%) in the overall population, following procedure. The incidence was respectively 6% in CG and 8% in EMG (p=0.78). It was defined as mild in 10 patients (5 in the EMG and 5 in CG, p=0.99), moderate in 1 EMG patient and severe in 3 patients (2 in the EMG and 1 in CG, p=0.99). Within EMG, the 2 patients with severe haematoma required early re-intervention for surgical pocket revision: one of them was on treatment with VKA, with an HAS-BLED score of 4 and a pre-procedural INR of 1.5; the other patient was on treatment with acetylsalicylic acid and ticagrelor. Within the control group, the patient with severe haematoma was on treatment with acetylsalicylic acid, clopidogrel and VKA on temporary LMWH bridging. This patient did not need a re-intervention and was strictly observed until complete resolution.

The occurrence of pocket haematoma was not correlated to the type of mobilization following CIED implantation, as described in Table IIIB. Indeed, all patients with evidence of surgical pocket haematoma were on baseline treatment with some antiplatelet agent and/or anticoagulant agent. No any pocket haematoma was observed in patients that were not on treatment with any of such drugs. Conversely, the occurrence of pocket haematoma was significantly associated with administration of any drug predisposing to bleeding (incidence 9% vs. 0%, p=0.02).

DISCUSSION

The optimal management of patient mobilization after CIED procedure has been an issue for a long time. However, specific recommendations are still lacking and only few observational studies investigated the possible complications of early mobilization[13–15]. As a result, each centre developed its own protocol and currently most operators recommend immobilization for at least 24h after CIED procedure.

The few observational studies from the ’80s -’90s about early mobilization not only reported contradictory results, but were also difficult to compare: most of these studies did not include any control group and results were compared against same-centre complication rates.

Among more recent studies, in 2003 the retrospective study by Villaba et al.[16] included both hospitalized patients and outpatients undergoing CIED procedure and did not found an higher rate of complications in patients mobilized early. In 2005 Miracapillo et al.[17] published the unique randomized trial available in literature on early mobilization after CIED procedure: they randomized 134 patients into 2 groups (early and late mobilization) finding no significant differences as to complication rates. In that study patients were not equally divided (because 57 were allocated in early mobilization group and 77 in the standard group), furthermore patients were followed-up for 2 months. Our results are in accordance with those of Miracapillo. In fact we did not find any significant difference in the complication rate between standard mobilization (24 hours) and early mobilization (3 hours), proving the safety and feasibility of an earlier mobilization. A significant contribution of our analysis, compared to previous studies, is certainly the higher numerosity (200 patients), the 24-months follow-up, the real-world enrolment including also patients needing urgent implantation and the equal allocation of patients among groups.

The complication rates in the present study are consistent with those reported in literature[18–24]. In the study of Miracapillo, it was observed a PL dislodgement rate of 3,8% (vs. 3,5% in the present study). Reintervention was required in 3.5% patients (4.3% in the study by Lee et al.[22], 9.2% in the study by Pakarinen et al.[24], 5.2% in the study by Haug et al.[20]).

Anyway, as PL dislodgement depends mainly on a progressive fibrosis mechanism developing over several months, the mobilization within the first day after implantation (either early or delayed at 24 hours) is probably an irrelevant factor on this type of complication.

Pocket haematomas were correlated with the assumption of at least one drug predisposing to bleeding, according with studies by Ghanbari et al.[25], Birnie et al.[26] and Kutinsky et al.[27]. Independently from randomization group, all haematomas occurred in patients on treatment with one or more antiplatelet agents and/or anticoagulant agents.

Limitations

This study was not designed to evaluate hospitalization length. Indeed, most patients were afferent from the emergency room and presented with comorbidities that could prolong hospital stay independently from the randomization group. Although we think that Gilchrist bandage alone has a

limited usefulness, we didn’t evaluate early mobilization without Gilchrist bandage support because of prudential reasons as aforementioned. Further studies designed with these purposes will need to answer this point.

CONCLUSIONS

The E-Motion trial proves that early mobilization at 3-hours after CIED procedure does not imply higher rates of intra-procedural complications or 24-month lead dislodgment compared with standard mobilization at 24 hours. A shortening of immobilization period after CIED procedure is safe and feasible. So, it might be possible same-day implantation and discharge.

FIGURE LEGENDS

Figure 1 - Gilchrist bandage

Figure 2 - Freedom from PL dislodgement following intervention.

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AUTHOR CONTRIBUTIONS

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