ZAMAR CAREPACE™

A new method for lowering post-procedural risks in devices implant

*Fabrizio **Caravati** MD(1), Chiara **Minoia** MD(1), Lorenzo **Doni** MD(1), Alessandro **Orrù** MD(1), Roberto **De Ponti** MD(1), Edordo **Verna** MD(1), Jorge Antonio **Salerno-Uriarte** MD(1).*

(1) Cardiology Center, Hospital Circolo & Fondazione Macchi, Università dell'Insubria, Varese, Italy

Corresponding Author

MD. Fabrizio Caravati

Cardiology Center, Hospital Circolo & Fondazione Macchi, Università dell'Insubria

Viale Borri 57, 21100, Varese, Italy

fabrizio.caravati@alice.it

Disclosures:

Dr Caravati received minor consultant fees for Boston Scientific.

Acknowledgment

Thanks to Mr. Giuliano Villa for technical support and valuable suggestions on the improvement made on the device.

INTRODUCTION

It is well known that in the first 24 hours after devices implant of (pacemaker/ICDs), there are risks (sometimes considerable due to age, physical shape of the patient or his medical history), to develop major complications that can compromise the patient's clinical status and lengthen hospital stay (as well as increase costs for the hospital or clinic).

Hematoma is one of these complications, especially in patients using anticoagulants or antiplatelet agents (the majority of cardiological patients) (**1**), which very rarely can be interrupted before the procedure. In case of hematoma there is also an increased risk of developing infections, which is a more serious complication for the patient and expensive for the hospital (cost is linked to the cost of complex and risky procedures for leads extraction, necessary in these cases) (**2**). The risk of infection is related to the hematoma itself as pabulum of germs, and procedures for the overhaul of the pocket that are necessary to evacuate the bulky hematomas.

Another important complication is the displacement of the electrodes, which occurs more frequently when the mobilization of the limb is early, and maximum in the first 24 hours (**3**). Also this complication requires re-operation, with all the necessary inconvenience for the patient and increased costs and the average length of stay. (see **Tab. 1**).

Until now, the patient was instructed (not always completely cooperative, for example because of advanced age) not to move the ipsilateral arm pacemaker in the first 24 hours to avoid the displacement, and ice was applied locally to prevent hematoma.

These devices are obviously empirical and insufficient for the above-mentioned reasons.

AIM

To evaluate the feasibility, efficiency and cost-effectiveness of the new system CARAPACE™ in lowering the rate of complications in the post procedural period after devices implantation as well as cost-saving for hospital.

METHODS AND PATIENTS

CAREPACE™ SYSTEM

The system is composed of an elastic band, with a compressive cushion placed at the pre-pectoral level; glycolic no tox liquid runs inside a coil thanks to a cooling unit (supplied by Zamar, Suzzara-MN, Italy). The pump can be set to work at fixed temperature around 4°C or with programmed cycles of different periods (from 0°C to 8°C). Pressure connections can be easily removed also by the patient himself – i.e. to go to the - without turning the unit off.

In our study the system has been working for 24 consecutive at a fixed temperature of 4° C.

PATIENTS

We studied 20 consecutive patients (15 M, 5 W, average age 61 $\pm$ 11 years) who underwent devices implantation.

The system was applied immediately after implantation in Electrophisiology Room, without any need of dressing. Once the patient was in department, the system was connected to the cooling pump and set at 4°C and left working for 24 hours; it was disconnected only at his request to to to the bathroom. After 24 hours the unit was disconnected and only the elastic band was left until hospital discharge, usually the day after implantation.

FOLLOW-UP

All patients were checked on the day of discharge, by inspection of the wound, electronic control of the device and chest radiography in anteroposterior.

A first clinical follow-up was performed after 10 days, at removal of stitches with inspection of the wound, and after one month from the implantation, with inspection of the wound and electronic control of the device.

STATISTICAL ANALYSIS

Continuous variables were expressed as mean±SD

RESULTS

All the patients tolerated very well the system both for compressive elastic band and the cooling temperature set by the devise. Only two patients complained of the machine noise, but it has never been necessary to give up the treatment. There were no malfunctions in the system and the dressing was easy for the health staff; only once, due to the implantation in the right subclavian site, it has been necessary to adjust the bandage because of the non-conventional position, without prejudice to effectiveness or efficiency.

The possibility of providing bandages for this type of opposed systems is still under study.

The time spent by medical staff for dressing, setting and connection of the equipment was minimal (less than 10 minutes per patient).

There were no lead displacement in acute pre-discharge, and all patients except one were discharged on postoperative second day. In the latter case an additional day of observation was necessary because of a major allergic reaction to the antibiotic administered on the day of the procedure.

In two patients on oral anticoagulation therapy, we observed the formation of a small hematoma not tense, which did not require reoperation or length of stay. Already at 10 days follow-up in the removal of stitches, the hematoma appeared in resorption, and finally resolved at the month follow-up.

DISCUSSION

The simplicity of the system, combined with the excellent results obtained in this preliminary study, and the excellent tolerability of the system by the patient, configures CAREPACE™ as useful, feasible, efficient and cost-effectiveness. Considering the cost of complications related to device implant, and their reduction in terms of minimizing risk and discomfort of the patient, and in terms of reduction of costs related to the possible repetition of surgical procedures and increased hospital days, the CAREPACE™ system is to become a standard device in the postoperative period of patients submitted to subcutaneous device implantation.

LIMITS

The number of patients tested is low, and although preliminary results are encouraging, it is necessary to increase the casuistry to reach acceptable statistical significance. For the time being an opposed version of the bandage for the right implants is not available (currently under study), although, as was previously stated, you can adjust the bandage with good results.