ASUGI
Azienda Sanitaria Universitaria Giuliano Isontina

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

INFORMATION FOR PATIENTS UNDERGOING IMPLANTATION OF BIVENTRICULAR PACEMAKER (CRT)

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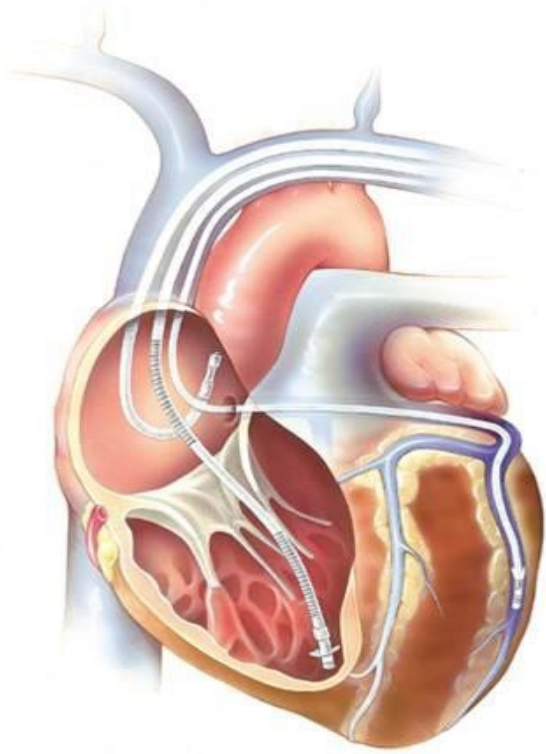

PURPOSE OF THE PROCEDURE

The biventricular pacemaker (CRT) is capable of stimulating the right atrium (or in any case sensing any spontaneous atrial activity) and both ventricles separately and allows a more harmonic contraction of the walls of the heart.

Data from literature and from controlled clinical trials suggest that CRT can improve quality of life, reduce hospitalizations for heart failure and

mortality. The benefit in terms of improvement in cardiac function and symptoms is expected, regardless of the correctness of the procedures implemented, in about 70% of patients.
The CRT is a small device and consists of a battery and an electronic circuit, connected to the heart through 3 electric wires called electrocatheters, positioned respectively in the right atrium, in the right ventricle and inside a vein, the coronary sinus, which from the right atrium reaches the external wall of the left ventricle.

DESCRIPTION OF THE PROCEDURE

The operation is performed under local anesthesia and usually lasts **between 90 and 180 minutes**: the duration of the operation depends on various factors, in particular on the highly variable anatomy of the coronary sinus, which cannot be predicted a priori.
Discharge from hospital usually takes place 24-48 hours after the operation. The operation begins with a skin incision of about 4 - 6 cm, generally under the left clavicle, which serves to prepare a space ("pocket") under the skin for housing the device.
From here the electric wires (electrocatheters) are then inserted through one or more veins and will be positioned inside the heart under radiological control.
For the most complex part of the procedure (positioning the electrode for left stimulation in a peripheral branch of a vein - the coronary sinus - reachable from the right atrium), it is necessary to administer a liquid visible on X-rays (contrast medium), **CONTAINING IODINE**.
Subsequently some electrical measurements are performed, in a similar way to what is done during the implantation of pacemakers, the

electrodes are connected to the stimulator and finally some subcutaneous and cutaneous stitches are performed to close the wound.

POSSIBLE COMPLICATIONS

Possible complications of the treatment are divided into intraoperative and postoperative.

The most frequent **intra-operative** complications include pocket bleeding, pneumothorax, coronary sinus lesions, blood effusion in the pericardium, severe arrhythmias (bradycardia or tachycardia). The treatment of these complications can include additional interventions, even invasive, which can prolong the subsequent hospitalization. Sporadic cases of death during the procedure have been described in medical literature.

The most frequent **post-operative** complications (occurring in the days or weeks following the procedure) include serum-blood effusion in the subcutaneous pocket, erosion of the skin overlying the stimulator or the leads, thrombosis of the arm veins, localized or systemic infections, displacement of the leads from their initial location with the need to reposition them.

Incidence of complications are shown below according to data from medical literature (1st column) and in our Center in 2018 (2nd column).

Type of implantation	% in literature data	% in our Center
Atrial/ventricular electrode dislocation	1 - 18%	**3.5%**
Pneumothorax	1,1 – 2.25%	**0.5%**
Pocket hematoma	0.5 – 4.58%	**0.23%**
Infection/decubitus	0.5 – 2.27%	**0.5%**
Pericardial effusion	0.1 – 0.8%	**0 %**
Subclavian vein thrombosis	0.44 – 0.7%	**0 %**
Transient lesion of the cardiac veins	2.5 - 6%	**0%**
Other pocket revision needs (e.g. tenderness without infection)	unknown	**0.5 %**
Patient death		**no one**

Finally, **rarely (5 - 10%), there may be the technical impossibility to position the catheter adequately in the left ventricle and to complete the implantation.**

Although the devices are subject to very rigorous checks, they can be subject to potential malfunctions (e.g. premature battery discharge, electrode breakage) which make it necessary to replace them. This happens very rarely and interventions are timely, especially in remotely monitored patients.

AFTER THE PROCEDURE

In general, the period necessary for functional recovery is about 15 days in order to allow adequate healing of the surgical wound; the

sutures are removed after about 10 days.

After discharge from hospital, it is necessary to follow all the prescribed provisions and treatments; in particular, there are periodic checks (1-2/year) which must be done in our or another electrostimulation center authorized to check the CRTs.

After the implantation of the CRT, it will no longer be possible to be exposed to strong magnetic fields (such as those used in magnetic resonance or in arthrosis magnetotherapy) or to therapeutic electric currents (such as those used in neuromuscular stimulation).

After CRT implantation, exposure to strong magnetic fields, in particular used for diagnosis or therapy, should always be reported, in order to evaluate the feasibility and methods of performing the diagnostic test (for example nuclear magnetic resonance) or treatment (magnetotherapy, neuromuscular stimulation).

After CRT implantation there may be limitations to driving and sporting activity (transient, or permanent but already justified by the underlying pathology, therefore not due to the presence of the device).

FORESEEABLE OUTCOMES OF NON-TREATMENT

I have been explained that if I decide **NOT** to undergo the surgery, I will give up the benefits offered by the surgery, in particular the improvement of symptoms, heart function and the increase in life expectancy.

SCARS

Scars are represented by a surgical scar (4-6 cm long) below the left

clavicle; you can also see the swelling caused by the device (about 5 mm thick) at the level of the scar.

SPECIAL WARNINGS

ALLERGY TO IODINE

The procedure may include the need to administer a contrast agent containing iodine. Patients with previous allergic episodes following administration of iodine or angiographic investigations must undergo particular medical treatment (pre-medication with antihistamines and cortisone) in the previous 24 hours.

ALLERGY TO ANTIBIOTICS

ANTIBIOTICS are given before the procedure and for 24 hours afterward for the prophylaxis of infections. Any allergies to antibiotics must be promptly reported.

PREGNANCY

Due to the use of X-rays, it is necessary to inform the doctors of a possible pregnancy or pregnancy in progress.

THE PROCEDURE WILL BE CARRIED OUT BY ONE OR MORE OF THE FOLLOWING DOCTORS:

- **dr. Massimo Zecchin**
- **dr. Bianco Elisabetta**
- **dr. Luca Salvatore**
- **dr. Fulvia Longaro**

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