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RESEARCH ARTICLE

Technique of the cardiac resynchronization therapy device implantation. One center's experience in Republic of Moldova.

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Abstract

Introduction: Cardiac resynchronization therapy has become an established treatment modality for patients with advanced heart failure and left bundle branch block.

In 2016 we started the implantation of the cardiac resynchronization therapy devices in Medpark International Hospital and for the first time in The Republic of Moldova. Taking into consideration the lack of the experience we had to face the challenges and quickly implement all the published data. From April 2016 till April 2023 in our center were implanted 49 cardiac resynchronization therapy devices.

Objective: The purpose of the current article is to describe our technique of cardiac resynchronization therapy device implantation and the subsequent follow-up of the patients.

Technique: We describe in detail our technique providing explanation for every step and discussing about alternative ways to perform certain step. We describe some complications that could arise and our strategy to avoid them.

Discussion: Our technique is a result of the knowledge obtained from a lot of recent published data and personal experience. Despite the fact that the number of the cardiac resynchronization therapy procedures performed in our center is small in comparison with other centers, we made an effort to gradually improve our technique.

Conclusion: Cardiac resynchronization therapy is an important tool in heart failure management. The implantation could be a challenging procedure and many complications could arise. Is important to develop a proper strategy to face all the challenges.

Keywords: Cardiac resynchronization therapy; coronary sinus, hearth failure; implantation technique; left bundle branch block; Republic of Moldova.

Abbreviations

AV – Atrioventricular
CRT - Cardiac resynchronization therapy
CRTD - Cardiac resynchronization therapy with defibrillation
CS – Coronary sinus
EF – Ejection fraction
EP - Electrophysiology
INR – International normalized ratio
LBBB - Left bundle branch block
LV - Left ventricular
PADIT - Prevention of Arrhythmia Device Infection Trial
RA - Right atrium
RV - Right ventricular

INTRODUCTION

Cardiac resynchronization therapy (CRT) has become an established treatment modality for patients with advanced heart failure. QRS delay, especially left bundle branch block (LBBB) impairs cardiac function by intraventricular dyssynchrony, atrioventricular (AV) dyssynchrony and interventricular dyssynchrony. CRT partially or totally corrects AV dyssynchrony, interventricular dyssynchrony and most importantly left ventricular dyssynchrony.[1]

Many randomized trials confirmed the beneficial effect of CRT the fact that is reflected in the current international guidelines.[2]

Taking into consideration that the heart transplant is not easily available in some countries the CRT is a crucial step for survival in patient with left bundle branch block and heart failure with reduced ejection fraction.

In 2016 we started the implantation of the CRT devices in Medpark International Hospital and for the first time in The Republic of Moldova. Taking into consideration the lack of the experience we had to face the challenges and quickly implement all the published data.[3] From April 2016 till April 2023 in our center were implanted 49 CRT devices all the devices being cardiac resynchronization therapy with defibrillation (CRTD).

CRT device implantation could be a challenging procedure and many complications could arise. It is important to develop the proper strategy to face all the challenges.

OBJECTIVE

The purpose of the current article is to describe our technique of CRT implantation and the subsequent follow-up of the patients.

TECHNIQUE

Patient selection

We follow the current ESC 2021 guidelines[2] to select the patients for implantation of CRT devices. CRT is especially recommended (Class I Level A) in patients with ejection fraction (EF) ≤ 35%, QRS ≥150 ms and LBBB who remain symptomatic despite optimal medical therapy.

Preparation

Our routine preparation for the procedure of CRT implantation is:

1) Stopping/adjusting anticoagulants. If the patient is taking direct oral anticoagulants, we

give the last dose 24-48 hours before procedure for Rivaroxaban and 12-24 hours for Dabigatran or Apixaban. In case the patient is taking Antivitamin K anticoagulants (Warfarin, Acenocoumarol) and international normalized ratio (INR) > 2.5 we stop them 2 days before procedure. If INR is ~ 2 we do not stop the anticoagulants.[4]

2) The placement of the peripheral venous catheter at the same side where the device is implanted (usually left side for CRTD patients). In case the venogram of the cephalic, axillary and subclavian veins will be necessary, is important to have the venous catheter at that side.

3) Administration of 2g intravenous Cefazolin 30-60 minutes before procedure (or 3g in patients over 120 kg). In case the patient is allergic to cephalosporin we give 1g Vancomycin infusion 2 hours before procedure. In 2022 we implemented the routine use of the Prevention of Arrhythmia Device Infection Trial (PADIT) score to predict the risk of infection.[5] In case the PADIT score is ≥ 5 points we administer oral antibiotic therapy for 5-7 days.

Anesthesia

We use local anesthesia with Lidocaine in all our patients. If the patient has allergy to Lidocaine, we use Bupivacaine or Articaine. We usually prepare 3 syringes with 4 ml Lidocaine 2% diluted with 6 ml Sodium chloride 0.9%. According to the patient status and operator preference we use sedation with 1-6 mg Midazolam and 25-100 μg Fentanyl in some patients or deep sedation with continuous Propofol infusion in a very anxious or unstable patients.

Venous access

There are several techniques of the venous access for the CRT lead placement: cephalic vein preparation, subclavian vein access and axillary vein access.

Our current preference is the use of axillary vein to obtain the access.

We selected the axillary vein approach as a routine technique taking into consideration several advantages. When compared to subclavian puncture technique, axillary vein puncture permits to obtain the venous access in the extrathoracic portion of the venous system and thereby to avoid pneumothorax and to prevent lead fractures. We had no pneumothorax complications when the technique was respected, nevertheless had some cases of pneumothorax when subclavian vein access was chosen.

Some centers use ultrasound to guide axillary vein puncture, some use blind technique with anatomical landmarks, some use X-ray landmarks to guide the axillary puncture. Our practice is the use of X-ray guided axillary vein puncture technique described by Burri H. et all in 2005.[6] Our target point is the confluence of the 2nd and 3rd rib, where the vein is usually located. With fluoroscopy guidance we advance the needle pointing toward the head of the patient at a 45-60° angle to the skin surface until the blood is aspirated. Care has to be taken to not cross the medial border of the 1st rib to avoid pneumothorax.

If the venous access is challenging, we inject about 10 ml of contrast agent (Iohexol 350 mg/ml) diluted with 10 ml 0.9% sodium chloride in the peripheral venous catheter to obtain the image of the cephalic, axillary and subclavian veins (Figure 1). The venogram is used as a reference for vein puncture. It is especially useful in upgrades from pacemakers to CRT when some patients could have obstructions of the axillary or/and subclavian veins.

Figure 1. The venogram showing the cephalic, axillary and subclavian veins

Pocket creation

In case a CRTD device is implanted a subpectoral generator implantation has to be taken in consideration to avoid skin erosion in frail patients. If the subcutaneous tissue is well developed there will be no issues if the prepectoral generator implantation is chosen. Our current preferred choice is subpectoral pocket creation that provides better cosmetic results and prevents skin erosion.

Leads placement

During CRT placement three leads are implanted: right ventricular (RV) lead, left ventricular (LV) lead and right atrial (RA) lead. The RA lead has to be implanted even in patients with permanent atrial fibrillation taking into account the possibility of sinus rhythm restoration and arrythmia discrimination algorithms. The LV lead is placed in the left heart via the coronary sinus.

The LV lead placement is technically difficult and time consuming.

Currently, we use only single coil RV leads for CRTD devices. There are no additional benefits of the use of dual coil RV leads and additional difficulties could arise if RV explantation is necessary in case of device infection.[7,8]

Some operators start with CS lead placement as is most challenging, but the majority perform RV lead placement first. Our current technique is to place and secure first the RV lead. That approach permits to have additional landmarks for CS cannulation.[9] When the RV lead is in place we could better understand where the CS ostium is located searching in the proximity of the RV lead curve. Additionally, we have the lead in place in case the emergency pacing is needed.

The most important and challenging step in LV lead placement is CS ostium engagement.

Different techniques were developed and described to cannulate the CS: direct cannulation with CS sheath, the use of electrophysiology (EP) deflectable catheters,[10] the use of coronarography catheters (AL2, MP catheters).[10,11]

Our current approach is the use of the several consecutive techniques:

1) Firstly, we try to cannulate the CS ostium using CS sheath. Initially, we place the J shaped guidewire in the RV. After that we push the CS sheath over the guidewire and place it over the tricuspid valve (nearby the RV lead curve). Then we pull back the guidewire and rotate the CS sheath counterclockwise. With that rotation the tip of the CS sheath usually jumps in the CS ostium. We inject some contrast to confirm the CS ostium engagement, and if confirmed, cannulate the CS with the guidewire and thereafter with the CS sheath over the wire.

2) The next technique to cannulate the CS is the use of EP deflectable catheter. For that purpose, we usually use 6F or 7F deflectable EP ablation catheters. The advantage of the technique is the fact that the catheter shape could be changed adjusting to CS ostium position and the tip of the EP catheter is round, thereby the risk if the CS dissection is lower. After cannulating the CS with the EP catheter, we push the CS sheath over the EP catheter inside the CS.

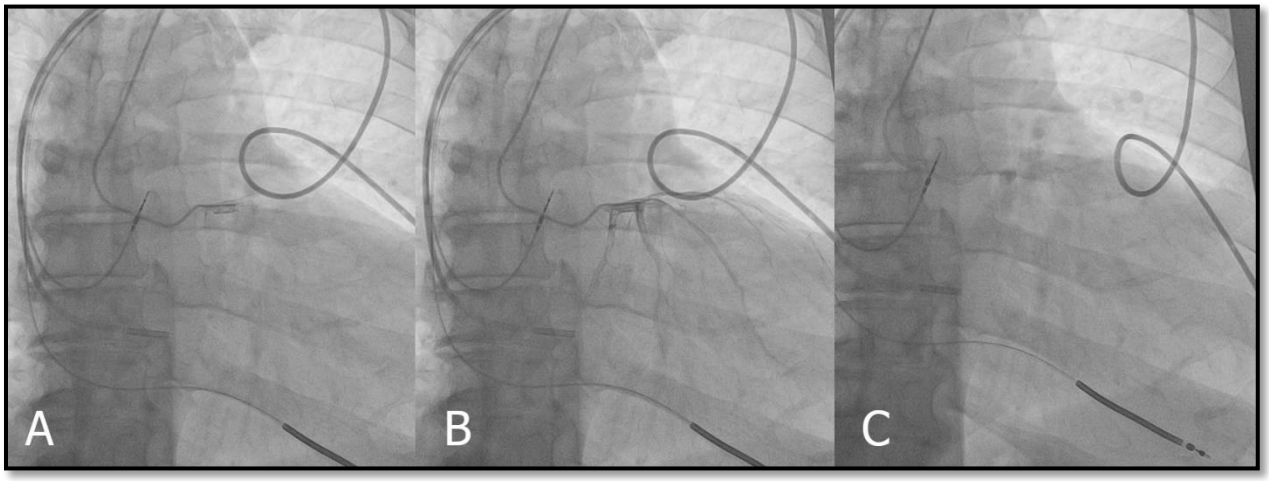
3) Another technique to find the CS ostium in difficult cases is the use of small amount of contrast agent. As we find the CS ostium, we engage it directly with the CS sheath or with the J shaped guidewire.

4) If none of the previous techniques permits us to cannulate the CS ostium, the next one is to perform the coronarography with venous phase to understand the CS anatomy and use the venogram as a reference image (Figure 2).

5) In some challenging cases we need the use of coronarography catheters as AL2, MP to enter the CS ostium.

6) In case of the failure of all mentioned techniques we postpone the procedure for other session, use left bundle branch area pacing[12] or refer to cardiac surgeons for epicardial LV pacing.

Figure 2. Coronarography.
(A) The catheter in left main coronary artery, (B) Arterial phase, (C) Venous phase with contrast agent draining in the venous system and showing the coronary sinus.



Target vessel

The next step in LV lead placement is the choice of the target vessel. We usually perform the venogram of the CS without CS balloon in left anterior oblique 30° projection. Nevertheless, the majority of the authors underline the importance of performing occlusive venogram of the CS using balloon.

Our target area for LV lead placement is posterolateral or lateral branches. If there are no suitable branches in that area we aim for anterolateral branches. There could be cases with no suitable vessels for LV lead placement either being too small or absent. In such cases our option will be epicardial implantation of the bipolar lead on the LV lateral wall or to consider left bundle branch area pacing[12]. This is why we always keep in our hospital a CRT device with bipolar LV lead port.

We initially cannulate the target branch with 0.014 inch floppy wire and thereafter advance the LV lead over the wire. If the cannulation of the target branch is impossible due to the angulation of the vessel, we introduce an angiographic catheter in the sheath (for example 4F vertebral catheter) to engage the branch vessel and to send the floppy inside.

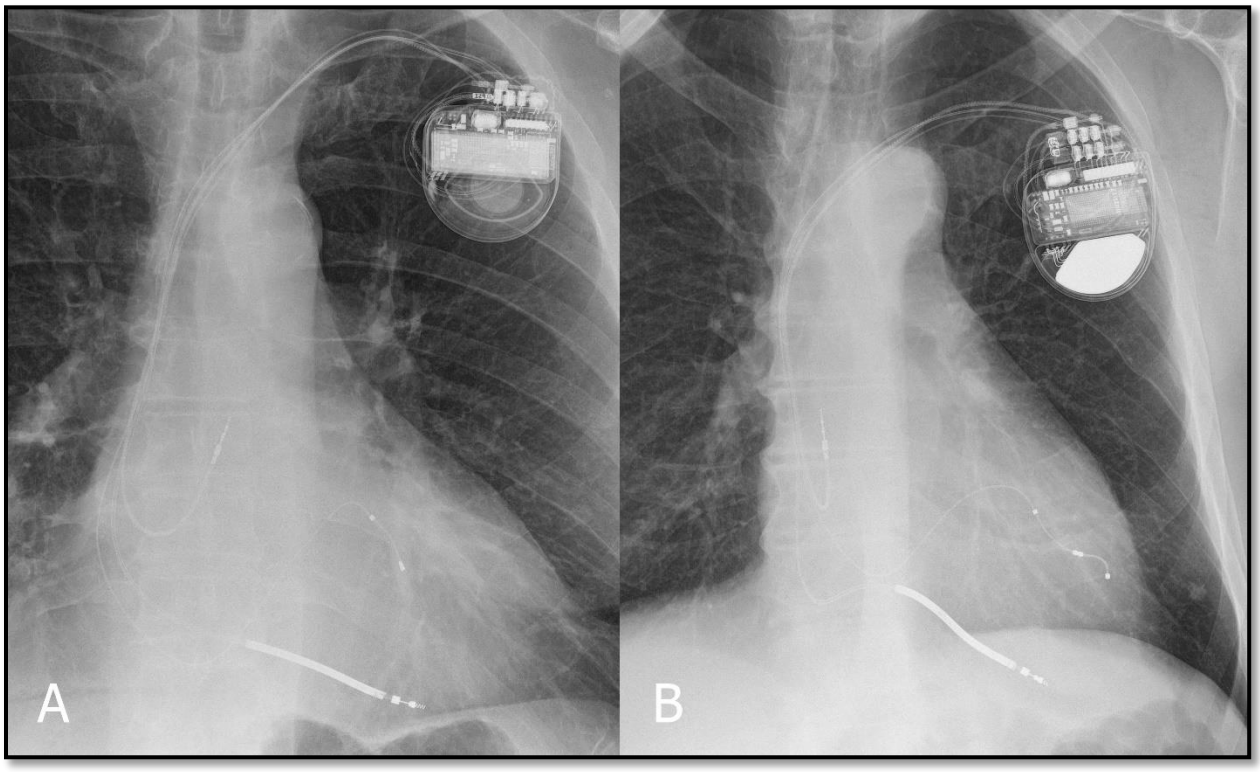
In the majority of the cases, we use standard 0.014 inch floppy, but sometimes, we need some extra support 0.014 ich floppy guidewires to send the LV lead in the target vein.

Types of the left ventricular leads

There are bipolar and quadripolar LV leads for CRT (Figure 3). There are several advantages of the quadripolar leads described in the literature.[13] We can confirm from our experience as well the benefits of the quadripolar leads. Using quadripolar LV leads we have much more vector possibilities for LV pacing. There are many situations where the vector has to be changed to deal with diaphragmatic stimulation after procedure, increase in LV pacing thresholds, or loss of LV capture.

There are also many types of LV lead shapes: straight, S shape, L shape, etc. In the last years we use LV leads with S shape. It permits us to have easy access of the lead to the target branch and to have good stability after implantation.

Figure 3. Types of left ventricular leads
(A) Bipolar L-shape and (B) quadripolar S-shape left ventricular leads comparison.



FOLLOW-UP

In the next day after procedure:

1) We perform the X-ray in two projections (anteroposterior and lateral view) to check leads position and to exclude the pneumothorax.

2) Interrogate the device to check the parameters and to adjust if necessary.

3) Change the sterile wound dress.

4) We do not continue the routine antibiotic treatment after procedure. As was mentioned earlier we could continue the antibiotic if the PADIT score is high.

5) We discharge the patient.

The patient is invited for ambulatory consult one week and one month after the surgery. We check the wound and interrogate the device. In the majority of cases, we perform echo guided adjustment of the LV-RV delays. After 2 months we perform the complete transthoracic echocardiography exam to see the changes in the chamber size and EF.

Delay's adjustment

The CRT is very complex electronic device with a lot of adjustable parameters. We could pace both ventricles simultaneously (LV-RV

delay 0 ms) or with some delay. The adjustment could permit us to obtain the best synchronization of the LV contraction proved both by narrowest QRS on ECG and by visualization of the LV contraction on echocardiography. Our current practice is to adjust LV-RV delay using echocardiography. We check the LV contraction in parasternal short axis view and apical 4 chamber view choosing the best LV-RV delay.

As an option we can perform LV pacing only. In that case we have intrinsic RV activation and adjust only AV delay (PAV/SAV) to obtain best synchronization.

COMPLICATIONS

The CRT implantation could be a challenging procedure and many complications could arise. There could be intraoperative and postoperative complications. During the procedure the physician has to be aware of the risk of CS dissection or rupture, cardiac tamponade, hemodynamic instability, etc. Some complications could happen in the postoperative period as: pocket hematoma, lead dislodgement and pocket infection.

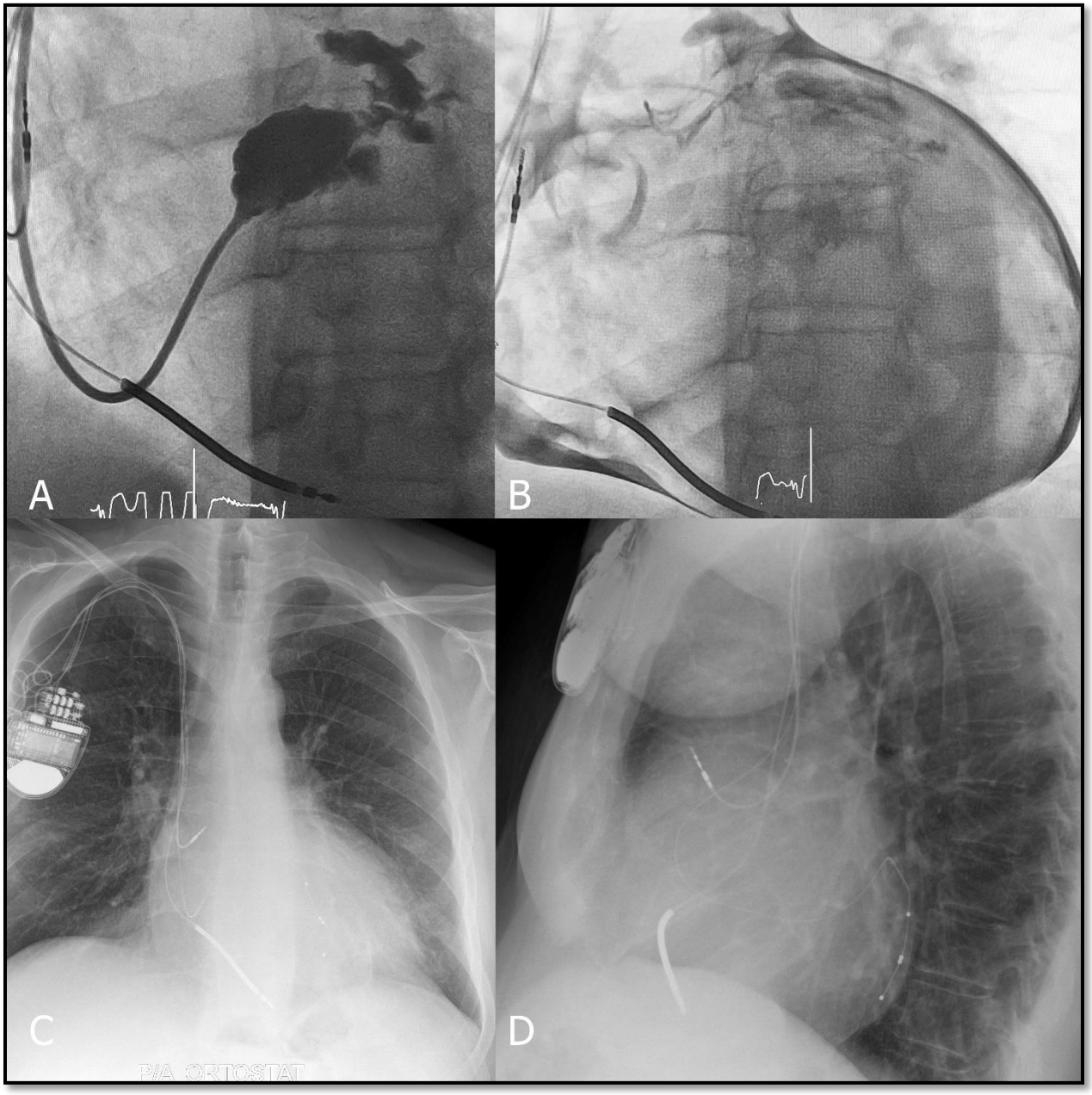
Hematoma

To avoid pocket hematoma formation, we do not use bridge therapy with anticoagulants.[4] We use electrocautery in all our patients to perform meticulous hemostasis and, if necessary, use 500 – 1000 mg local tranexamic acid to obtain hemostasis.[14] If after the use of tranexamic acid there is still a bleeding from the puncture site, we use figure of 8 suture to stop the bleeding.

Coronary sinus dissection or rupture

CS dissection or rupture is a known major complication during LV lead implantation. To avoid CS dissection is necessary to gently manipulate the sheath and the guidewires and to avoid introducing the contrast agent in CS with high pressure if the sheath is perpendicular to CS wall. We had one case of CS rupture that did not necessitate pericardial puncture, the CS lead was implanted in a postponed session (Figure 4). Usually, after 3-4 weeks the dissection or rupture is healed.

Figure 4. Coronary sinus dissection and rupture
(A) Coronary dissection and rupture can be noted after contrast injection.
(B) The contrast in pericardial space around.
X-ray of the same patient after successful left ventricle lead implantation in postponed session: antero-posterior view (C) and lateral view (D).



Lead dislodgement

To avoid lead dislodgement, we use active fixation for RA and RV leads. We recommend to the patient to avoid raising the elbow higher the shoulder level at the surgery side for 6 weeks.

Perforation and cardiac tamponade

Some patients that need CRT implantation could have apical aneurism of the LV or very thin myocardium. Sometimes is better to avoid screwing the RV lead in the apical region and is wise to choose safer places as septum.

DISCUSSION

CRT implantation is a challenging procedure that consists of many steps. Every single step is important to obtain a successful result. Without proper planning and training there could be challenges that are difficult to overcome.

The technique we presented is feasible and can be successfully implemented even in low-income countries. For example, not every center has the luxury of the access to the full spectrum of the LV leads, this is why is important to develop a technique that will fit to the center's possibilities and patient's needs.

EP specialists should have a back-up plan for every single obstacle in CRT implantation. What to do if cannot cannulate the CS? What if there are no proper target vessels for LV lead placement? How many hours should the procedure last? Is better to try a second session for LV lead placement or to switch to left bundle branch area pacing? All that questions should have an answer in the mind of the physician.

Our technique is a result of the merge of the knowledge obtained from a lot of recent published data and personal experience. Despite the fact that the number of the CRT procedures performed in our center is small in comparison with other centers, we made an effort to gradually improve our technique. There are still many improvements that has to be done.

CONCLUSION

CRT is an important tool in heart failure management.

The use of the therapy for correctly selected patients is decreasing the mortality, significantly increasing the quality of life, improves the EF of the left ventricle and postpone the need for heart transplant for years.

Taking into consideration that the heart transplant is not easily available in some countries the CRT could be the best solution for survival of the patient with LBBB and heart failure with reduced EF.

CRT device implantation could be a challenging procedure and many complications could arise. It is important to develop the proper strategy to face all the challenges.

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