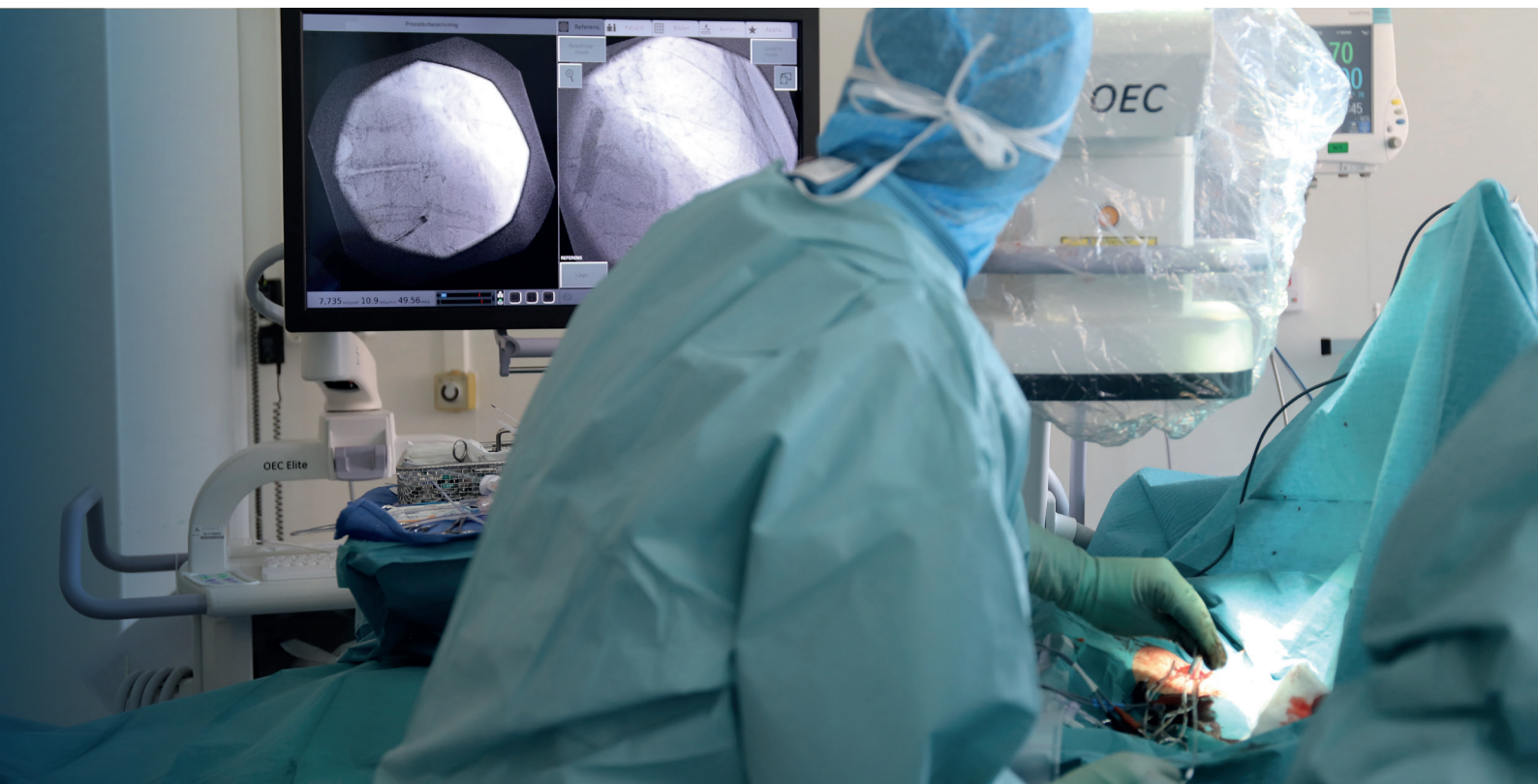




Optimizing patient care in an arrhythmia department

Dr. David Mörtzell, Director of device surgery and arrhythmology unit, Skane University Hospital, Lund (Sweden)

The arrhythmia department of Skane University Lund, with its remote electronic heart-monitoring system, performs up to 1700 procedures a year. About 60% of those more standard procedures are performed on the OEC Elite CFD Ergo C-arm. Dr. Mörtzell sat down with us to discuss his practice.



What are the economic challenges that your department is facing to optimize patient care?

Last year, we had a block-budget for 800 devices and 700 ablation procedures and we ended up doing about 1700 treatments. The additional cost was supported by our hospital administration because we demonstrated that it was necessary for the patients, and the patient outcome was positive. Compared to some other European countries where procedures are reimbursed on a fee-for-service basis, like lead extraction for example, we have a lower procedure volume. For additional

procedures over budget, we discuss patient benefit with the administration before proceeding. What is more important: performing device implantations or lead extractions?

Sweden is divided into 21 counties; each county has a different budget. In Skane county, we are evolving slowly towards performing more and more complex procedures in centralized departments. We have grants for lead extraction, and ablation to treat patients primarily from Skane county, but patients come from anywhere in Sweden. In addition, my department is specialized in children's heart diseases and Grown-Up Congenital Heart

disease (GUCH), for which we receive specific subventions. These subventions also cover lead extraction, which is relatively expensive. We are growing as a center of excellence for children's heart care therapy and GUCH. We are one of the largest centers in Sweden for these four patient groups. This allows us to apply for increased budgets to improve patient care.

What type of imaging lab do you use in Lund arrhythmia department and how do you triage the procedures among these rooms?

In the arrhythmia clinic we have two cathlabs where we primarily do ablation procedures. The complex heart rhythm treatments are performed in one of the cathlabs with two physicians, where we can use the Niobe (Stereotaxis, Saint Louis, MO USA) magnetically-driven robotic system. The department is a reference center for Stereotaxis. The other cathlab is equipped with a fixed angiography room setup for manual ablation and both labs are equipped with 3D mapping system CARTO® (Biosense Webster). In addition to the two fixed angio rooms, we built an additional room dedicated to device

surgery with the OEC Elite CFD Ergo C-arm (GE Healthcare) and an imagiQ2™ surgery table (Stille). We have one shared hybrid room in the surgery department that I can use for some procedures twice a week. We also have access to the children's surgery department on demand (approximately once a week), that is also equipped with a C-arm. We are one of the two reference centers for children's heart surgery and arrhythmia treatment in Sweden, together with Sahlgrenska University hospital.

What are the most demanding procedures in terms of fluoroscopy?

I think that lead extraction is the most demanding procedure for fluoroscopy. We need to see the lead extraction tool, i.e., a special sheath, and position it in a controlled manner over the lead to break the fibrous tissue that makes the lead adhere to the vessels and heart muscle. Fluoroscopy imaging is used to make sure that the sheath is aligned with the lead. If the sheath deviates from the lead, we can damage it, or even break it. This procedure can be long.

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We perform standard extractions on the OEC Elite CFD C-arm when the lead has been in place for only a few years and calcified fibrous tissue has not had time to develop over the lead and where the lead design is standard and not fractured. The most complex extractions are performed in the fixed hybrid room. We routinely perform this procedure under general anesthesia in the hybrid operating room in case we need to do an emergency sternotomy, as we are unable to do this down here in the EP Lab.

Balloon cryoablation is a standard procedure performed at Skane university Hospital - Lund as a primary

intervention to treat atrial fibrillation. This procedure is performed using fluoroscopy alone to guide the catheter containing the balloon, to inflate the balloon, and check that we have a good occlusion of the pulmonary veins by the balloon before introducing the refrigerant liquid into the balloon and proceeding with the creation of scars in the heart tissue. For this procedure, there is no need for image fusion. The CT scanner is used to confirm the anatomy of the patient, checking that there are 4 separate pulmonary veins. We can then merge the CT images in the CARTO® mapping system, to create a 3D model of the heart chambers.

Some centers perform cryoablation using a very simple set up, with a C-arm and the ablation system. To be able to perform ablation, you need a high-quality left anterior oblique projection to do the trans-septal puncture. However, once you are in the left atrium, you can simply navigate with an AP projection and the electrical signal from a mapping catheter. In routine ablation cases, it is possible to perform ablation without fluoroscopy, as we know where we are in the heart just by looking at the ElectroCardioGram (ECG) signals.

Typically, if you have a standard case, you need just a few seconds of fluoroscopy to verify that the catheters

are in the heart, and in the position where you need to have them, and maybe you will need to perform fluoroscopy for another few seconds to check where your ablation catheter is. Thus, many procedures only have between 20 to 60 seconds of fluoroscopy time, and we can rely on 3D electroanatomical mapping systems and minimize fluoro, even if the procedure itself may be 2 hours or more. But, if our 3D mapping fails, we need to rely on fluoroscopy. For pacemaker implants, we use fluoroscopy to guide and position the leads. This is the main activity in this mobile room in the device surgery lab.

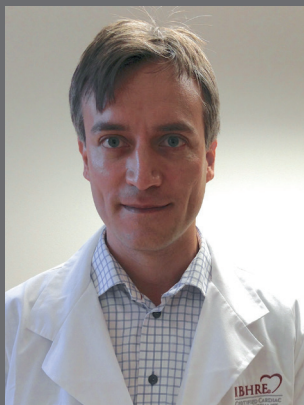
Why did you choose the OEC Elite CFD Ergo C-arm for your activity?

I am the referent for the choice of the C-arm in the clinic, but as it is a major investment, the decision is taken by the team within the heart-lung center.

The main criteria we examine when choosing a C-arm are: ease of use, well-designed and intuitive interface, and image quality/dose. It is important for me to try to limit my X-ray dose without compromising image quality, especially as some procedures take more fluoroscopy time. We are always screening in low-dose fluoroscopy mode, just increasing the dose with a Cine loop for the final check. Because

the OEC C-arm is easy to move, I can easily change the projection during the procedure, and optimize my exposure time thus minimizing the overall dose.

The image quality of the OEC Elite CFD C-arm is really good. I can clearly see the border of the heart as well as my leads and guidewires, and I have good visualization of the motion of the tip of the leads. The OEC Elite CFD C-arm performs well on low dose and IQ, and is easy to use, which are the two most important criteria. □



Dr. David Mörtzell
Director of device surgery
and arrhythmology unit,
Skane University Hospital,
Lund, (Sweden)

Dr Mörtzell - how did you train to become an arrhythmia specialist?

I started as a general medicine and emergency room physician and specialized in cardiology in 2006. As I had a preference for arrhythmology within cardiology, I completed my training during a fellowship at the EP lab at Royal Brompton Hospital (London, UK). On my return to Sweden I decided to specialize in invasive arrhythmology. So I moved from interventional cardiology to invasive arrhythmology. Since then I perform only electrophysiology procedures and device surgery with a split in my activity of about 50% EP ablation and 50% device surgery.

How do you manage the quality of care within your arrhythmia department?

As director of arrhythmia devices, I define what procedures we are going to do, how we are going to do them, and we report the number of procedures with their associated cost. I define the routines, how we do the

procedures, and I define the training courses for the staff and other physicians. We work in collaboration with device companies for training courses and I am responsible for the relations with them. In addition to managing the patient workflow, I am also responsible for ensuring that we work within our quality charter requirements, optimizing for example X-ray exposure time and fluoroscopy protocols. But I also work 100% as a clinician as well. On a national level, we contribute with research projects, such as the multicentric evaluation of new cryoballoon ablation techniques¹.

How do you foresee the evolution of device and arrhythmology procedures in the future?

The trend for arrhythmia procedures is to move towards leadless devices through percutaneous access. If you are asking me where we will be in 5 years, I would say that subcutaneous ICDs will be the largest portion of ICD procedures. This type of device implantation does not require

fluoroscopic imaging guidance. We just need to perform a quick final control image to check the positioning of the device, that is located under the muscle, and the position of the defibrillator lead connected to the device, that is placed under the skin, over the ribs, and over the sternum, creating a defibrillation field. The implantation of leadless pacemakers will also become widespread. This device, which is no larger than a big vitamin pill, is brought directly into the right ventricle via the inferior cava vein using a delivery system through femoral vein access. The device is anchored directly to the heart tissue. The implantation procedure duration is shortened as there are no leads to be placed inside the heart. For this procedure, fluoroscopy is used to guide and position the device. Today, radiation exposure is a concern for young doctors. They are training with mapping systems, navigation systems, 3D models, and when something happens and they do not have these tools available, but just fluoroscopy imaging, they are lost, they don't know how to read the image. Teaching them how they can perform simple procedures using fluoroscopy alone, and only one catheter, relying on ECG signals is an important part of training. It is important to be able to manage our procedure with minimalistic equipment and effective fluoroscopic imaging while at the same time, learning how to use more sophisticated mapping tools. □

¹ "Cryoballoon vs. radiofrequency ablation for atrial fibrillation: a study of outcome and safety based on the ESC-EHRA atrial fibrillation ablation long-term registry and the Swedish catheter ablation registry". Mörtzell D et al. Europace. 2019 Apr 1;21(4):581-589.

The statements by GE's customers described here are based on their own opinions and on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.



The arrhythmology unit is a sub-division of the hospital's heart-lung center.

The center comprises the cardiology department, itself divided into 3 subsections: ischemia (including Percutaneous Coronary Interventions), structural heart interventions and heart failure, and the arrhythmia clinic.

The EP activity of Skane University Hospital is split between two departments, one located in Malmö and one located in Lund. In Malmö regular pacemakers are implanted in up to 600 patients per year.

Lund's EP department has been developing its activity in more advanced procedures, training the staff to perform the programming of the devices itself. The department is equipped with a remote electronic heart-monitoring system where the data saved on the device is

transmitted to the clinic through a transmitter in the patient's home. Regular reports are sent to the clinic so the medical staff can check the diagnostic data, modify the programming of the device if needed, and feed the database. This electronic system allows us to increase patient safety while saving costs and time to concentrate the medical staff on patients with the greatest needs¹. The volume of procedures is about 700 ablations, 400 Implantable Cardioverter Defibrillators (ICDs), 300 CRTs, 500 pacemakers, 100 lead extractions, and a number of congenital treatments per year. For ICD and pacemaker activities, patients are mainly recruited in the county of Skane. For pediatric care, complex CRT, lead extraction, and ablation in GUCH, patients come to the ward from the entire country.

¹ <http://skanecare.com/care-projects/>

Complete Atrioventricular (AV) block treatment with Cardiac Resynchronization Therapy (CRT) device implant using the OEC Elite CFD Ergo C-arm

Courtesy of Dr. David Mörtzell, Director of device surgery and arrhythmia clinic, Skane University Hospital, Lund (Sweden)

OEC Elite CFD Ergo C 21 cm, VAS MTS

Clinical Challenge

CRT device implantation (or biventricular pacing) is a common treatment for cardiac arrhythmia. The procedure involves implanting a pacemaker under the skin below the collarbone, connecting the pacemaker to three leads: one inside the right atrium, one inside the right ventricle, and the third one inside the coronary sinus vein at the level of the left ventricle of the heart.

The leads are brought to the heart through venous access, from the subclavian vein to the superior vena cava. Fluoroscopy is used to guide the different leads to their final anchorage location.

While the guidance of the leads in the right atrium and right ventricle is quite straightforward, the cannulation of the coronary sinus can be more complex. In addition, the third lead needs to be guided to the great cardiac vein, and placed into one of

its bifurcations using a 0.014" guidewire.

As the procedure can be long and is performed under fluoroscopy guidance, with demanding image quality, radiation exposure must be managed during the procedure, optimizing each step.

Solution

The procedure was performed with assistance of X-ray imaging from OEC Elite CFD Ergo C. To control the exposure, the fluoroscopic guidance of the leads was set to standard pulse mode at 15 pps. Coronary sinus venogram was performed in Digital Cine 15 pps mode. The anatomic profile was set to General HD to navigate 0.014" guidewires.

Clinical example

An 80-year-old female patient with a history of chronic heart failure presented with a left bundle branch block. She was

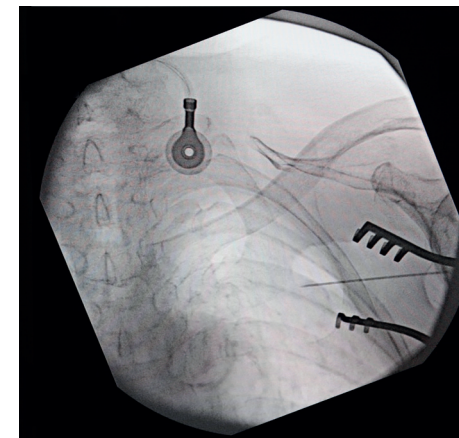
treated 6 months earlier for pulmonary edema and received optimal pharmacological treatment but remained highly symptomatic and left ventricular function stayed poor. The patient was thus eligible for a CRT device implantation.

This procedure was performed under local anesthesia, under ambulatory conditions.

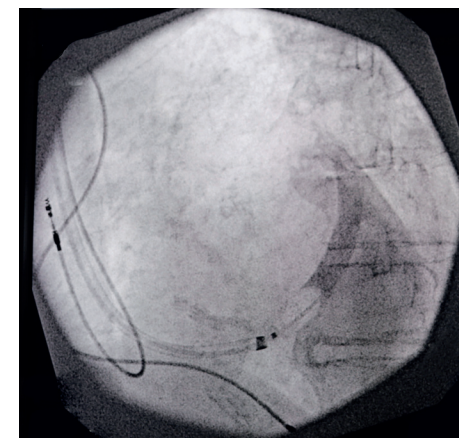
Venous access was obtained by axillary vein puncture. Catheterization and subsequent venogram of the coronary sinus was performed injecting about 20 cc of iodine at 50% dilution.

The final verification of the lead was performed and compared to a post-op X-ray control image. The same information was found in both the fluoroscopy control and X-ray images.

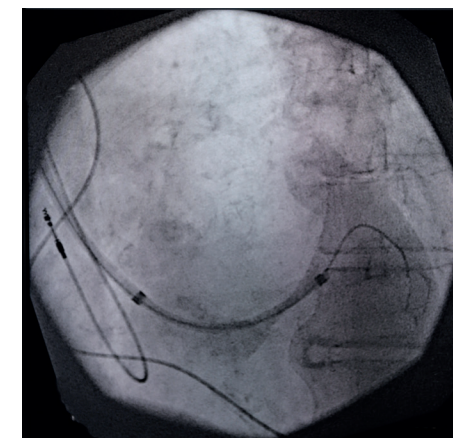
The total exposure time was 1 minute and 20 seconds, and the total DAP was 11.7 Gy cm².



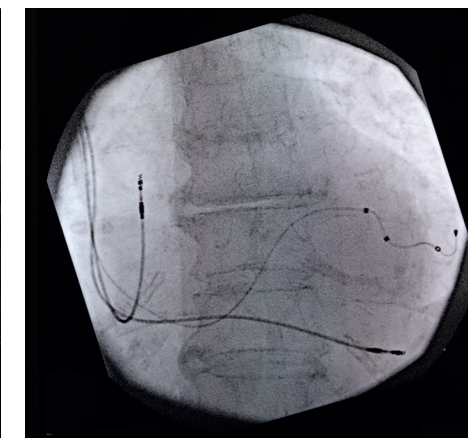
Puncture of axillary vein – Antero Posterior (AP) View.



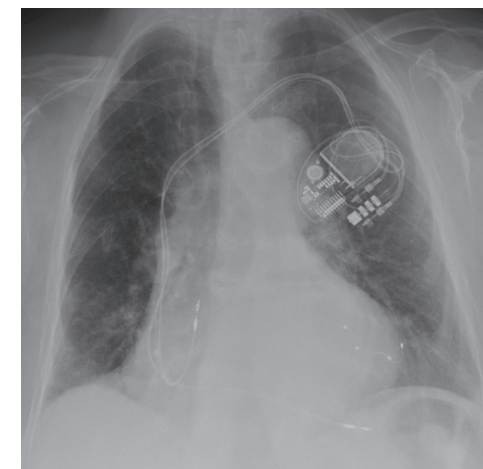
Coronary sinus injected with contrast media 30° Left Anterior Oblique (LAO).



Catheterization of coronary sinus – 30° LAO.



Final perioperative control of CRT leads in coronary sinus – AP view.



X-ray control post procedure AP view.

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Pacing treatment with leadless device implant using the OEC Elite CFD Ergo C-arm

Courtesy of Dr. David Mörtzell, Director of device surgery and arrhythmia clinic, Skane University Hospital, Lund (Sweden)

OEC Elite CFD Ergo C 21 cm, VAS MTS.

Clinical Challenge

Pacing devices are evolving towards systems without leads. The advantage of such devices is that they require no lead guidance and no surgical pocket under the skin. Potential complications associated with venous access (such as pneumothorax), lead dysfunction and local symptoms from the surgical pocket (such as hematoma or infection) are less likely. The device (Micra™ Transcatheter Pacing System – TPS Medtronic), which is no larger than a large vitamin pill, is brought directly into the right ventricle via the inferior vena cava using a delivery system through femoral vein access. The device is anchored directly to the heart tissue without external leads.

Solution

The procedure was performed with assistance of X-ray imaging from OEC Elite CFD Ergo C. The guidance of the delivery sheath was achieved using continuous fluoroscopy. The verification of the anchorage of the device on the heart tissue was performed in Digital Cine 15 pps mode. The anatomic profile was set to General HD. In order to visualize the small anchor tines located at the extremity of the device and ensure that there is no

dislodgment, the magnification mode was used during live fluoro control.

Clinical example

An 85-year-old female patient with a history of chronic atrial fibrillation and bradycardia was offered this treatment instead of a conventional pacemaker in ambulatory conditions. This device implant

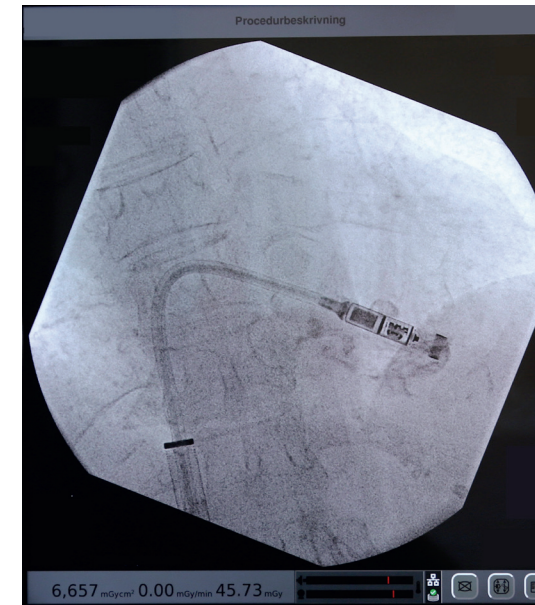
placement requires only femoral vein access, and no other incisions during the procedure, potentially reducing post-op complications.

Femoral vein access was performed under local anesthesia.

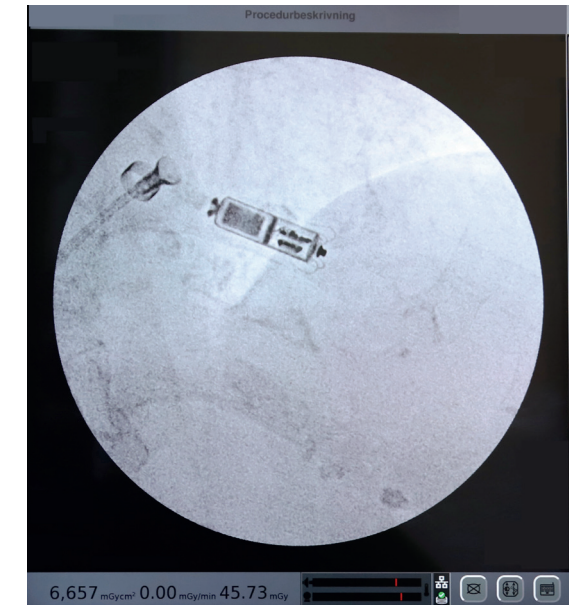
The total exposure time was 1 minute and 53 seconds, and the total DAP was 6.6 Gy cm².



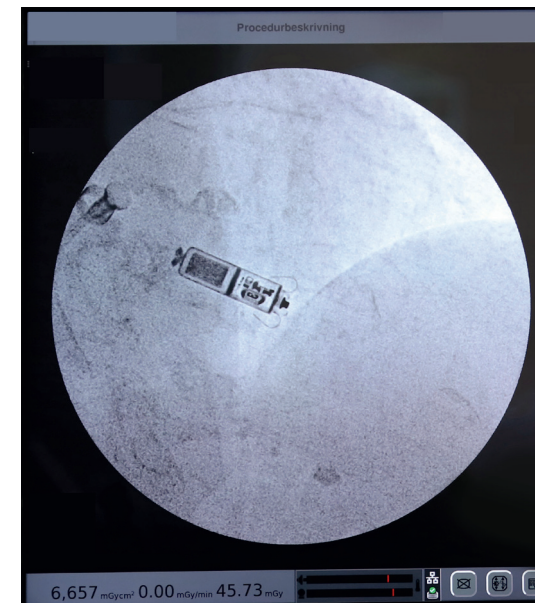
Preparation of the device delivery sheath.



Placement of the device next to heart tissues – AP view.



Release of the device from delivery system – AP view, Magnification 1.



Final verification of device implantation – 30° Right Anterior Oblique (RAO) view, Magnification 1.