CRT Implantation Without Lead Apron

Given the duration of less than six minutes, the average fluoroscopy time for a complete Mediguide Technology-controlled CRT implantation is far lower than conventional exposure.

By Hildegard Kaulen
Photos: Andréas Lang

Hindricks likes to chart new territories. He is considered one of the pioneers of cardiac catheter ablation and manages one of the worldwide leading centers for rhythmology. Each year, his department performs 1,200 atrial fibrillation catheter ablations and around 500 CRT implantations. Recently, Hindricks started to break new ground. About nine months ago, he began implanting biventricular pacemakers using MediGuide™ Technology integrated into his Artis® zee system – and, thus far, the Heart Center in Leipzig, Germany, is the only clinic in the world doing it.

Hindricks is aiming to significantly reduce radiation exposure for patients and interventionalists, and seeks to further improve the quality of interventions. If the electrodes of the biventricular pacemaker are optimally positioned, cardiac status can improve and morbidity and mortality decrease almost without side effects – in fact for many years.

To date, Hindricks and his team have completed fifty MediGuide Technology-supported CRT implantations. They would have completed more but the supply of necessary equipment like sheaths and guidewires for non-fluoroscopic catheter navigation wasn't in full swing until recently. "Cardiac resynchronization therapy is the most important innovation in heart failure treatment in the past 10 years," Hindricks explains. "All clinical studies proved that patients live longer and better with it, since the technique leads to an improvement in cardiac function. And, there is a clear medical need for more CRT implantations." In Germany, 202 treatments per million inhabitants occur each year, which ranks as number two in the European care statistics. The majority of eligible patients, however, do

Cardiac Resynchronization Therapy (CRT)

CRT is indicated and effective for:
- Advanced drug-refractory heart failure
- Severe LV systolic dysfunction
- Ventricular dyssynchrony

CRT improves:
- Symptoms of heart failure
- Exercise capacity
- Ventricular function and structure
- Heart failure-related hospitalizations
- Mortality risk


Non compensated Cineloop Selected
[Cine #1] [0006] SID: 95 CA: 0 RAO: 0
Turn Magnet OFF
Landmark
View
Cineloop
Angio Survey™ 3D
EP Cath
Port3
SVC
CS OS
CS Ref
More Land marks
Show LM
Undo Last
Non compensated Cineloop Selected
[Cine #2] [0000] SID: 98 CA: 0 LAO: 40
Motion Sensor: valid
Ready For Cineloop
114 BPM
Schrittmacher

not necessarily receive this treatment. According to Hindricks, this is due to a lack of awareness among referring physicians. In many countries, the technique is not covered by insurers, and electrophysiological (EP) centers, as well as appropriately trained physicians, are not available. "We must overcome existing roadblocks and develop better screening programs," he comments. "The left ventricular electrode must be placed in a safe and suitable position. If complications arise, they normally are related to the intervention and include dislocations or infections," he adds.

How Does the MediGuide Technology Work?

MediGuide Technology is not a new mapping system but a cardiovascular treatment platform for fluoroscopy-free navigation. It can be used whenever devices are navigated under fluoroscopic control inside the body. The position of the device is determined by magnetic tracking, and projected in real-time to a pre-recorded cine loop. "The characteristics of MediGuide Technology are its built-in compensation algorithms," Hindricks explains. "The devices are depicted independent from primary and secondary organ movements. This provides high precision over time, resulting in 4D catheter tracking. Moreover, the fluoroscopy system and the electromagnetic sensor field do not work independently, but are fully registered." Compensation of respiratory and cardiac movement is enabled by a reference sensor in the patient's sternum. This sensor acts as a reference point for the calculation of the catheter position. The electromagnetic field transmitter is mounted inside the fluoroscopy detector. Conventional CRT implantations are associated with considerable radiation exposure. This is caused by the anatomically and technically challenging implantation of the left ventricular electrode, a process that usually requires continuous fluoroscopy. During this procedure, the interventionalist stands near the left shoulder of the patient and probes the coronary sinus by means of left anterior oblique (LAO) projections, thus being exposed to considerable scattered radiation. So, they would also benefit from a reduction in the duration of fluoroscopy procedures. Moreover, the C-arm would not interfere with the interventionist's work, as the patient is no longer exposed to fluoroscopy during the intervention. Consequently, the implanter is able to navigate in an LAO projection without a C-arm occupying this position. "The catheter can be visualized on pre-recorded cine loops even during prolonged periods of examination. We can, therefore, have fluoroscopy performed only at the beginning and at the end of a CRT implantation," Hindricks says. "I dream of an electrophysiological laboratory that doesn't use lead aprons. I think that we will be able to implement this vision in the very near future."

Study Proves Decrease of Radiation Exposure

There is substanstive data to back-up Hindricks' vision. During the 50 MediGuide Technology-supported CRT implantations completed, radiation exposure could be reduced significantly compared to the conventional procedure. The average fluoroscopy period for LV electrode positioning was less than three minutes, and for the entire implantation less than six minutes, without any increase in the rate of complications. "I am absolutely convinced that we can reduce the fluoroscopy duration even further," the electrophysiologist says. "We still are in an early stage and use fluoroscopy during the intervention for safety-related reasons. In case of an uncomplicated anatomy, already today a catheter can be navigated safe and reliably without fluoroscopy. In case of stenoses and anomalies of the coronary sinus, we still need it as a safety precaution. As soon as improved algorithms of navigation are available, this will no longer be necessary."
So which MediGuide Technology-supported devices are already available for Hindricks? During CRT implantation, he uses a CS sheath and a subselector, both equipped with a MediGuide Technology sensor. The electrophysiologist reaches the target coronary vein by means of a guidewire of 0.14 mm diameter with the MediGuide Technology sensor, which is used to place the electrode in a suitable tributary of the main cardiac vein. The electrode itself is not equipped with a sensor. "This will not be changed in the near future," he says.

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Professor Gerhard Hindricks, MD
Heart Center of Leipzig University, Leipzig, Germany

"The electrode shall retain its proven design." Additionally, sensor-equipped diagnostic EP catheters are available as needed.

While the radiation exposure of MediGuide Technology-supported CRT implantations is considerably lower than in conventional procedures, the time expenditure is actually higher. Hindricks and his team need about 20 additional minutes (140 minutes compared to the average CRT implantation time of 120 minutes). "The increased time still reflects our study situation," he comments. "We enter new territories and are the first and only clinic in the world utilizing this procedure in CRT. With this in mind, the additional time expenditure is remarkably low. Nevertheless, intervention times are crucial for the hospitals. They should at least be comparable, if not even better than for the conventional procedure. I know that we have to improve, and I am convinced we will succeed."

Short Training Curve

Will other interventionalists adapt to MediGuide Technology? "The system offers one of the shortest learning curves you can imagine," Hindricks says. "We had colleagues who were familiar with it already after 10 minutes time, which was not only due to the fact that they were excellent electrophysiologists. Due to the projection of the catheter onto a conventional fluoroscopic image, we stay within an environment that is well-known to all users. They obtain additional imaging quality, but no basically new views. This helps them to quickly become accustomed to the MediGuide Technology system."

While CRT facilitates a longer and better life for most patients, one quarter of the patients equipped with such a device are non-responders. Hence, Hindricks also uses the MediGuide Technology to understand the reasons for treatment failure. "Non-responders presumably require an individualized therapy," the electrophysiologist says, "not standard therapy." Therefore, he measures the phase shift between the electrically and mechanically activated myocardial areas. This shift reduces the heart's pumping efficiency. Since MediGuide Technology depicts this time delay at high temporal resolution, Hindricks and his team are able to measure the late points and use them to determine the position of the left ventricular electrode in an appropriate coronary vein, which is optimal for the patient. For this approach, they are currently collecting data. First results are promising.

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