SIEMENS

White paper

Siemens angiography and MediGuide™ Technology facilitate significant dose reduction during Cardiac Resynchronization Therapy (CRT)

Evidence shows reductions in fluoroscopy time and radiation exposure of up to 90%

Executive summary

Cardiac Resynchronization Therapy (CRT) device implantations are often associated with high radiation dose exposure due to long procedure and fluoroscopy times.

A first in human study recently conducted at the Heart Centre Leipzig (Germany) proved the benefits of using a novel sensor-based MediGuide™ Technology (St. Jude Medical Inc., St. Paul, MN) in combination with the Artis zee angiography system (Siemens Healthcare, Forchheim, Germany) for CRT implantations [1].

The study showed reductions fluoroscopy time and radiation exposure of up to 90% when compared to conventional (exclusively fluoroscopy-guided) CRT implantations. There were no negative consequences on procedural efficacy and no complications.

The study showed reductions in fluoroscopy time and radiation exposure of up to 90% when compared to conventional (exclusively fluoroscopy-guided) CRT implantations.

Background CRT and MediGuide™ Technology

CRT is a well established therapy for patients with advanced Heart Failure (HF). The number of implantations is rapidly increasing worldwide. In the US and Europe together, more than 150.000 CRT devices are implanted each year.

In conventional CRT device implantations all three leads are placed under fluoroscopic control. Due to long procedure and fluoroscopy times, CRT device implantations are associated with the risk of high radiation exposure for both patients and clinical staff. During this procedure, the interventionalist stands near the left shoulder of the patient and probes the coronary sinus using left anterior oblique (LAO) projections, thus being exposed to considerable scatter radiation.

Recent publications by the US Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA) strongly recommend the minimization of radiation exposure to patient, operator, and EP laboratory staff in keeping with the "As Low As Reasonably Achievable" (ALARA) principle [3] [4].

While the placement of leads in the right atrium and right ventricle require minimal time and dose, lead placement of the left ventrical (LV) lead is much more challenging due to the technical and anatomical difficulties of accessing the target location. It follows that most of the procedure time and radiation exposure is required for LV lead placement. Hence, this step of the procedure benefits most from the dose saving potential of using MediGuide™ Technology combined with the Artis zee angiography system.

Keywords

- *Cardiac Resynchronization Therapy (CRT)*
- *Device implantation*
- *Dose reduction*
- *Electro-magnetic navigation*
- *MediGuide™ Technology*

MediGuide™ Technology is a novel sensor-based electro-magnetic navigation system which can be fully integrated into Siemens interventional angiography systems. MediGuide™ Technology can be used whenever MediGuide™ enabled devices (e.g. catheters, guidewires etc.) are navigated inside the body under fluoroscopic control.

The position of the device is determined by magnetic tracking based on a field transmitter inside the fluoros-copy detector and a miniature-sensor inside the tip of the device. Currently, various MediGuide™ Technology-enabled devices are available including sheaths and guidewires for placement of a left ventricular (LV) lead during CRT implantation as well as designated catheters for cardiac ablation therapy.

Real-time motion-compensated projection of the device tip onto (one or more) pre-recorded fluoroscopy scenes allows device navigation and placement without x-ray exposure.

In addition to a considerable reduction in dose exposure, MediGuide™ Technology offers the option to operate in a virtual biplane mode including the preferred LAO (Left Anterior Oblique) projection while the C-arm is parked in an anterior-posterior or even right anterior oblique position. This enables unrestricted access to the patient device pocket from the left side. Especially in complex coronary venous anatomy, a virtual biplane mode can be useful to overall enhance the operator's orientation and navigation in the 3D space.

Results

In the study performed in Leipzig using MediGuide™ Technology and the Siemens Artis zee angiography, CRT devices were successfully implanted in all patients. The total procedure duration was 116 ± 43 minutes, the median total fluoroscopy time was 5.2 (Q1–Q3, 3.0–8.4) minutes, and the median fluoroscopy time for LV lead deployment was 2.6 (Q1–Q3, 1.6–5.6) minutes. The median total radiation exposure given as dose area product (DAP) was 10.7 (Q1–Q3, 6.9–17.4) Gy*cm^2 for the complete CRT system, of which 9.2 (Q1–Q3, 6.1–16.2) Gy*cm^2 were for the LV lead placement. No severe complications requiring acute intervention or reoperation were observed during the peri- and postoperative periods.

Data from 600 EP procedures performed using MediGuide™ Technology and the Artis zee system at the same center show that electro-magnetic navigation can lead to substantial dose reduction in a wide spectrum of cardiac catheter ablation procedures (e.g. atrial flutter, atrial fibrillation and ventricular tachycardia) [2].

"I dream of an electro-physiology lab without lead aprons.

I think we will be able to implement this vision in the very near future."

Professor Gerhard Hindricks, M.D.,
Heart Center of Leipzig University,
Leipzig, Germany

To quantify the potential of dose reduction due to MediGuide™ Technology use, total radiation exposure published by the Leipzig group [1] was compared to published data from similar studies on radiation dose exposure for patients and staff during CRT implantation (**Fig. 1**). The DAP values in procedures using MediGuide™ Technology were 90.4% lower than reported by Butter et al. [5] and 91.6% lower than those published by Brambilla et al. [6].

Conclusion

Radiation exposure, with its potential risks and harm to patients and operators, remains a major concern during cardiovascular interventions. The novel MediGuide™ Technology used in combination with the Siemens Artis zee angiography system allows for safe and successful CRT device implantation with substantial reduction in fluoroscopy time and radiation exposure. Compared with conventional, exclusively fluoroscopy-based CRT implantation techniques, a dose reduction of up to 90% can be achieved during implantations guided by electro-magnetic navigation.

Patients and study methodology

Fifteen patients with an established indication for a CRT device were implanted using the new MediGuide™ Technology to place the LV lead.

Data collection included demographics, clinical characteristics, adverse events and procedural data with a focus on procedure duration, fluoroscopy time and total radiation exposure. Patients were followed up for 4 weeks after implantation.

Special sensor-enabled delivery tools such as steerable catheters, sheaths, sub-selectors and guidewires are available and were used for non-fluoroscopic intubation of the coronary sinus and subsequent LV lead placement in a target side branch coronary vein. The sensors mounted on the tip of the various tools were displayed on the MediGuide™ Technology electro-magnetic navigation system using icons to show the position and spatial orientation of the sensor. The LV lead itself was not equipped with a sensor.

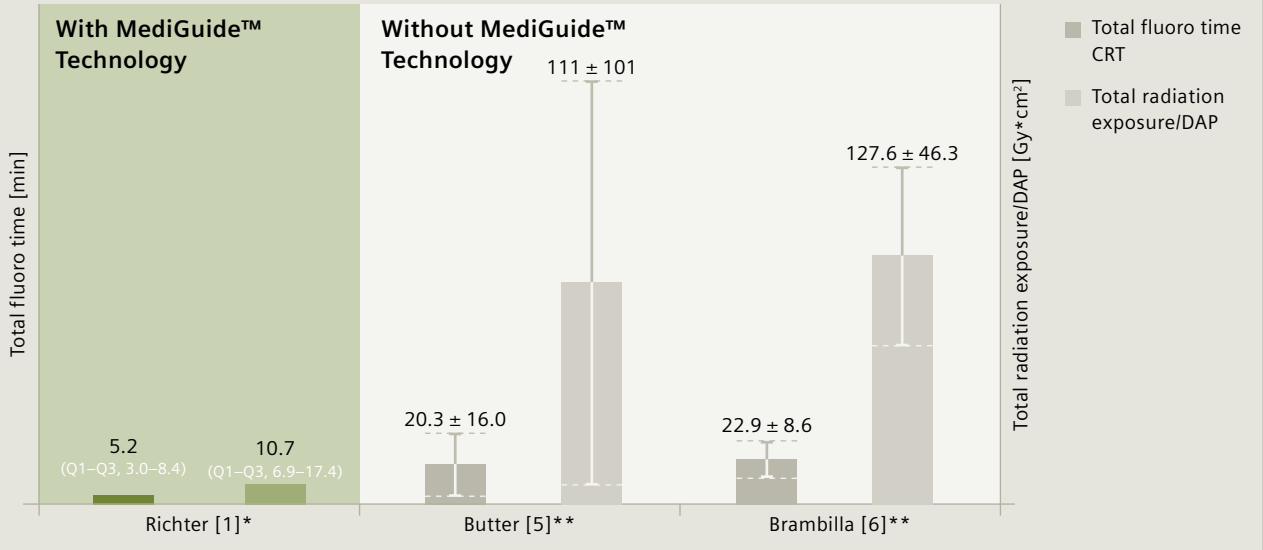

Fig. 1. Fluoroscopy time and radiation exposure with and without the use of MediGuide™ Technology

* values median and interquartile ranges ** values mean and standard deviation

References

[1] Richter S, Doering M, Gaspar T et al. Cardiac Resynchronization Therapy Device Implantation Using a New Sensor-Based Navigation System. Results From the First Human Use Study. *Circ Arrhythm Electrophysiol*. 2013; 6(5):917-923.

[2] Sommer P, Richter S, Hindricks G et al. Non-fluoroscopic catheter visualization using MediGuide™ Technology: experience from the first 600 procedures. *J Interv Card Electrophysiol*. 2014; Jan 16 [Epub ahead of print].

[3] Haines DE, Beheiry S, Akar JG et al. Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel, and Safety. *Heart Rhythm*. 2014; 11(8):e9-e51.

[4] Heidbuchel H, Wittkampf FH, Vano E et al. Practical ways to reduce radiation dose for patients and staff during device implantations and electrophysiological procedures. *Europace*. 2014; 16(7):946-964.

[5] Butter C, Schau T, Meyhoefer J et al. Radiation Exposure of Patient and Physician during Implantation and Upgrade of Cardiac Resynchronization Devices. *Pacing Clin Electrophysiol*. 2010; 33(8):1003-1012.

[6] Brambilla M, Occhetta E, Ronconi M et al. Reducing operator radiation exposure during cardiac resynchronization therapy. *Europace*. 2010; 12(12):1769-1773.

Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Telephone: +49 9131 84-0
Germany

www.siemens.com/healthcare

Legal Manufacturer
Siemens AG
Wittelsbacherplatz 2
DE-80333 Muenchen
Germany

Global Business Unit
Siemens AG
Medical Solutions
Angiography & Interventional
X-Ray Systems
Siemensstr. 1
DE-91301 Forchheim
Telephone: +49 9191 18-0
Germany

www.siemens.com/healthcare

Order No. A91AX-81472-19C1-7600 | Printed in Germany | WS 11140.5 | © 11.2014, Siemens AG

TH 460-140619