Anatomical factors involved in difficult cardiac resynchronization therapy procedure: a non-invasive study using dual-source 64-multi-slice computed tomography


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Aims

In cardiac resynchronization therapy (CRT) procedure, left ventricular (LV) lead implantation is time consuming. In this clinical setting, no study has investigated the impact of right atrium anatomical parameters on both CRT implantation procedure duration and X-ray exposure. Additionally, only few studies have examined the coronary sinus (CS) using dual-source 64-multi-slice computed tomography (DS 64-MSCT), and its impact on CRT procedure parameters has not yet been investigated. The aim of this prospective study was to identify local anatomical predictive factors of difficult CRT implantation procedure using DS 64-MSCT.

Methods and results

Between January and July 2010, 50 consecutive patients underwent primo CRT implantation. The patient population had a mean age of 70 ± 10 years, and was 34% female, with New York Heart Association Class 3.2 ± 0.3 heart failure, left ventricle ejection fraction 30 ± 4%, and QRS width 157 ± 30 ms. Cardiac resynchronization therapy implantation was attempted in 50 patients, and first LV lead implantation was obtained in 49 of 50 patients (98% primary success). One implantation failed (2%) due to unsuccessful LV lead implant. Procedure parameters were as follows: LV threshold, 1.4 ± 0.8 V; LV wave amplitude, 17 ± 8 mV; LV impedance, 830 ± 240 Ω; median procedure time (skin to skin), 51 min (38 min); median fluoroscopy procedure time, 11.9 min (22 min); and median LV fluoroscopic time, 10.3 min (22 min). In 10 patients (20%), procedures were difficult requiring an implantation lasting ≥ 85 min. The only predictive factor for difficult CRT implantation was the insertion level of the CS ostium (CSO), evaluated by the distance between the CSO and the bottom floor of the right atrium (14.8 ± 4 vs. 9.5 ± 4; P = 0.01). Neither the right atrium dilation nor right ventricular dysfunction was associated with difficult CRT implantation procedures.

Conclusions

Today, despite improvements in the materials used, problems still remain in the CRT procedure. In this clinical setting, the only predictive factor for very long CRT procedures is the CSO-level insertion (located high). This anatomical anomaly identified by DS 64-MSCT prior to surgery is responsible for 20% of difficult CRT device implantation procedures.

Keywords

Heart failure • Cardiac resynchronization • Unsuccessful implant • Procedure complications • Technical aspects • Cardiac computed tomography

Introduction

The efficacy of cardiac resynchronization therapy (CRT) has been demonstrated in highly symptomatic heart failure (HF) patients with wide QRS and depressed left ventricular (LV) function.1–6 Large randomized clinical trials reported positive long-term results in terms of symptoms, exercise tolerance, well-being, and CRT patients’ prognosis.3–10 However, two major issues should

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be addressed during the selection process of potential candidates in order to improve success rates. First, LV dyssynchrony appears to be an important predictor of CRT response. Secondly, attention should be given to venous anatomy in order to ensure that the area of latest activation can be reached through a suitable vein, particularly in patients with ischaemic cardiomyopathy, as the lack of a suitable branch of the coronary sinus (CS) may hamper successful endovascular branch. As a result, procedures may be long and difficult due to CS vein anatomy, need for CS angiography, and lack of operator experience. Although the availability of multiple lead designs and left heart delivery system (LHDS) options improves the procedure’s success, there are still difficulties, with a failure rate ranging from 5 to 15%, particularly for a primary LV lead implant. Risks associated with long CRT procedures have been clearly demonstrated including a higher risk of device-related infections (DRI) and radiation exposure which remains a challenge in CRT implantation procedures.

Some studies have been published looking for predictive factors of difficult implantation procedures, but their results are debatable due to several methodological issues. To our knowledge, no study has been performed using dual-source 64-multi-slice computed tomography (DS 64-MSCT), in order to investigate anatomical predictive factors of difficult CRT implantation. The aim of this prospective study was to determine the anatomical factors that are predictive of difficult CRT implantation procedure using DS 64-MSCT.

**Methods**

**Patient selection**

Between January and July 2010, 50 consecutive patients underwent primary CRT implantation. All patients included in the trial provided written informed consent. Inclusion criteria required that all the following conditions be met: (i) New York Heart Association (NYHA) functional Class III or IV HF; (ii) QRS width ≥120 ms with a left bundle branch block pattern or QRS ≥180 ms for paced patients (measured on three or more surface electrocardiogram leads); (iii) chronic LV systolic dysfunction defined by a left ventricle ejection fraction (LVEF) ≤35% and LV end-diastolic diameter (LVEDD) ≥60 mm on echocardiography; (iv) optimal medical treatment for HF, including angiotensin-converting enzyme inhibitors or AT1 receptor antagonists, diuretics, beta-receptor blockers, and spironolactone; (v) patients requiring atrioventricular node ablation for atrial fibrillation (AF) with moderate LV dysfunction (LVEF ≤40%) with or without QRS ≥120 ms, in line with the results of the PAVE study. Exclusion criteria were: (i) hypertrophic or restrictive cardiomyopathy; (ii) suspected acute myocarditis; (iii) correctable valvulopathy; (iv) acute coronary syndrome; (v) recent coronary revascularization (within the last 3 months) or planned revascularization; (vi) treatment-resistant hypertension; (vii) severe obstructive lung disease; and (viii) reduced life expectancy not associated with cardiovascular disease.

**Study design**

Between 5 and 30 days prior to implantation, patients underwent a clinical examination, 12-lead electrocardiography, transthoracic echocardiography, and Doppler evaluation.

Echocardiographic measurements: Transthoracic Doppler echocardiography was performed at least 24 h prior to the procedure by an observer who was blinded to the patient’s status. Ultrasound studies were performed using a Vivid 7 imaging system with a 2.5 MHz transducer (second harmonic activation). M-mode and bi-dimensional measurements were taken according to the recommendations of the American Society of Echocardiography. Right atrial anatomical two-dimensional echocardiographic measurements were performed. Right and left atrial surfaces were measured by planimetry (cm²). All two-dimensional echocardiographic and Doppler-derived pulmonary pressure measurements were averaged over five cardiac cycles. Tricuspid regurgitation was evaluated and considered significant when the grade was 3 or higher.

**Dual-source 64-multi-slice computed tomography**

Prior to CRT implantation, each DS 64-MSCT evaluation and measurement was conducted by an independent experienced operator (P.R.) who was blinded to the patient’s data. Imaging was performed using a 64-detector row Siemens SOMATON computed tomography (CT) scanners dual-source energy (Siemens Medical Systems, Erlangen, Germany). Overall, 80 and 110 mL of contrast material (Iomeron 400, Bracco Altana Pharma GmbH, Konstanz, Germany) were administered at an injection rate of 5 mL/min. Scanning was carried out using simultaneous acquisition of 64 sections with a collimated slice thickness of 0.5 mm. A segmental reconstruction algorithm allowed for including patients with a range of heart rates. Retrospective electrocardiogram gating was performed in order to eliminate cardiac motion artefacts. Data reconstruction was conducted on a Siemens Syngo post-processing workstation (Erlangen, Germany). During analysis, the observers were blinded to the participants’ group assignments.

Anatomic observations

Right atrium anatomical measurements were carried out. Right atrium surface was measured by planimetry (cm²) (Figure 1A and B). The tributaries of the cardiac venous system (Figure 2A) were identified on volume-rendered reconstructions. Afterward, the course of the veins was evaluated in three orthogonal planes using multiplanar reformatting. The presence of the following cardiac veins was evaluated: CS, anterior interventricular vein, middle cardiac vein, postero-lateral vein (PLV), posterior vein of the left ventricle, antero-lateral vein (ALV), and left marginal vein or lateral vein (LMV) (Figure 2B). Additionally, the number of side branches of these tributaries was evaluated. It was also noted whether tributary veins were tortuous or not.

Quantitative data

The CS ostium (CSO) was defined as the site where the CS makes an angle with the right atrium in the crux cordis area. Multiplanar reformatting was used to determine the size of the ostium in two directions. The distances between the proximal parts of the PLV, PV, LMV, and the CSO were measured. The CSO-level insertion (CSLI) was standardized and performed in a short axis view where the bottom floor of the right atrium was parallel to thoracic diaphragm muscle. The CSLI distance was measured from the lower edge of the CS to the tangent of the lower edge of the right atrium (see different examples; Figure 3A–C). Finally, the distance between the origins of the various venous tributaries was measured on volume-rendered reconstructions.

**Implant procedure**

The primary implant method was published elsewhere, as well as the antiseptic preparation. When this approach failed or the procedure remained difficult using the first approach, the operator was allowed to use conventional LHDS. Implantations were performed by the same experienced operator under local anaesthesia and...
conscious sedation, thus excluding the influence of the operator’s experience. In order to avoid bias, the implanter was blinded to the CT scan status. Total implant procedure duration (skin to skin), total X-ray time and Gy/cm², X-ray time and Gy/cm² for LV lead implantation, and pacemaker (PM) lead-related data (threshold, impedance, and amplitude signal) were recorded, as were complications during the procedure and post-operative period. In all patients undergoing implantable cardioverter-defibrillator (ICD) CRT, a defibrillation test was performed. All patients received a biventricular DDD-R device in the presence of sinus rhythm, and a biventricular VVI-R device in the presence of permanent AF.

Endpoints
The study’s primary aim was to evaluate both the prevalence and the predictive factors of difficult CRT implantation associated with long procedure duration using transthoracic echocardiography (TTE) and DS 64-MSCT. The definition of long procedure duration was based on the cut-off value associated with a higher risk of CRT DRI observed in previous studies. A median procedure duration ≥85 min was found to be independently correlated with a higher risk of CRT DRI. The following factors were tested: age, gender, body mass index (BMI), cardiovascular risk factors, device procedure category (CRT-P, CRT-D, or up-grading), aetiology of cardiomyopathy, NYHA class, LVEF, LV volumes and dimensions, presence of AF, systolic arterial pulmonary pressure level, right atrium dimensions, tricuspid regurgitation graduation, right ventricular function evaluated by tissue-Doppler imaging parameters (tricuspid annular plane systolic excursion), and lead position (ALV, PV, PLV, LV). All anatomical parameters evaluated by DS 64-MSCT were included in the analysis: right atrium dimensions and surface, CSO diameter, tortuous CS veins aspect, CSLI, number of CS target veins, and distance between the CSO and each CS target vein.

Re-intervention
Surgical re-intervention was defined as a surgical procedure required for non-infectious or infectious implant complications.

Follow-up
Prospective data included: (i) patient demographic and clinical characteristics; (ii) echocardiographic measurements; (iii) DS 64-MSCT evaluation and measurements; (iv) CRT characteristics (PM or defibrillator implantation, and primo implants or system upgrade of pulse generators or leads); (v) type of implanted device and number of leads; (vi) procedure duration (skin to skin) and total X-ray exposure, as well as LV lead procedure duration estimated by X-ray exposure; and (vii) occurrence of complications requiring re-intervention.
Patients were followed up by four experienced cardiologists. Electrocardiograms, device controls, and chest X-rays were performed the day after the procedure (Day 1) and on Day 5, just before patient discharge. Patients’ scars, sutures, and chest X-rays were examined in the outpatient clinic on Day 10 and at 3 months; a physical examination and device interview were also carried out at these examinations.

### Statistical analysis

All clinical variables were assessed at the time of the device implantation. The echo and 64-SCT parameters were evaluated during hospitalization by two operators who were blinded to the patients’ status. Continuous variables were presented as mean ± standard deviation or median with interquartiles as appropriate. Comparisons between the patients’ groups were performed on continuous variables using unpaired Student’s t-test or Mann–Whitney test as appropriate. Categorical variables were compared using \( \chi^2 \) tests or Fisher’s exact test as appropriate. Univariate logistic regression models were fitted in order to study the relationship between each covariate and the risk of prolonged procedure time. Backward elimination was used, removing the least significant variables at each step so as to elaborate multivariate models if necessary. A probability value of \( P < 0.05 \) was considered statistically significant. Coronary sinus ostium level insertion distance interobserver variability was assessed by a linear regression by two independent observers (P.R. and A.G.M.). All analyses were performed using StatView w5.0 (StatView IV, Abacus Concept, Berkeley, CA, USA).

### Results

#### Baseline population characteristics

Baseline clinical data are summarized in Table 1. The CRT implantation was attempted in 50 patients, and first LV lead implantation was achieved in 49 of 50 patients (98% primary success). One primary implantation failed (2%) due to the inability to keep stable the LHDS in the CS. In this case, the most sloping point of CSO and the tangent of the lower edge of the right atrium were at a height of 13 mm. Of the 50 patients, 40 were in sinus rhythm, 10 in AF, and 12 had a previous device (PM in 2 patients and ICD in 10 patients).

#### Implantation and technical aspects

Procedure parameters were as follows: LV threshold (1.4 ± 0.8 V); LV wave amplitude (17 ± 8 mV); LV impedance (830 ± 240 \( \Omega \)); median procedure time (skin to skin), 51 min (38 min); median of procedure fluoroscopy time, 11.9 min (22 min); median of LV fluoroscopic time, 10.3 min (22 min). The mean procedure time was 66.3 ± 39.5 min (30–150 min) and the mean X-ray procedure exposition time was 20 ± 22 min (3–85 min). In 10 patients (20%), procedures were difficult, requiring \( \geq 85 \text{ min for implantation.} \) The direct LV lead was successfully positioned as follows: lateral vein in 37 patients (74%), PLV in 10 patients (20%), and antero-lateral in 2 patients (4%). The mean fluoroscopy time for LV implantation was 18 ± 22 min (1–101 min). The device was an ICD in 38 cases (76%) and a PM in 12 cases (24%). The 50 devices implanted were CRT PMs in 12 patients (24%) and CRT ICDs in 37 patients (74%). As previously mentioned, the procedure failed in one patient who required a double-lead ICD device.

#### Predictive factors of difficult cardiac resynchronization therapy implantation (Table 2)

In 10 patients (20%), procedures were difficult requiring \( \geq 85 \text{ min for implantation.} \) The only predictive factor of difficult CRT implantation was the insertion level of the CSO, evaluated using posterior lip of CSO and the tangent of the lower edge of the right

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**Figure 3**

(A) The distance between the coronary sinus ostium and the bottom floor of the right atrium was measured and considered as reflecting the coronary sinus ostium-level insertion = 9.4 mm. (B) The distance between the coronary sinus ostium and the bottom floor of the right atrium = 20 mm (coronary sinus ostium-level insertion). (C) The distance between the coronary sinus ostium and the bottom floor of the right atrium = 4 mm (coronary sinus ostium-level insertion).
or not CS veins aspect, and BMI. Right ventricular dysfunction, LV lead definitive position, tortuous lead brand, inferior vena cava diameter, tricuspid regurgitation, factors, aetiology of cardiomyopathy, QRS width, device type, LV (ns): age, presence of AF, NYHA class, cardiovascular risk tested but did not correlate with CRT implantation difficulties. Procedures, nor were left atrial or right atrial dimensions or surfaces ventricular parameters were not associated with difficult CRT procedures, nor were left atrial or right atrial dimensions or surfaces or right ventricular dysfunction (ns). Several other variables were tested but did not correlate with CRT implantation difficulties (ns): age, presence of AF, NYHA class, cardiovascular risk factors, aetiology of cardiomyopathy, QRS width, device type, LV lead brand, inferior vena cava diameter, tricuspid regurgitation, right ventricular dysfunction, LV lead definitive position, tortuous or not CS veins aspect, and BMI.

Follow-up

During the follow-up period, which lasted a minimum of 3 months, re-intervention was necessary in 6% of patients (3 of 50): A local infection was observed in one patient and required an extraction without any specific tool (2%), and two LV lead dislodgements were observed (4%), requiring repositioning. Left ventricular leads dislodgements occurred 2 and 10 days after CRT implantation, interestingly the CLSI was measured at 13 and 20 mm, respectively, in two patients classified in the group of difficult implantation. Phrenic nerve stimulation was resolved with a lower output LV pacing or by changing configuration options.

**Discussion**

**Major findings**

Despite the availability of multiple lead designs and LHDS options, in practice, CRT procedures still remain difficult in an average of 20% of cases. In this clinical setting, the only anatomical factor related to both prolonged procedure time and X-ray exposure duration was the CSO position (high localization) evidenced by DS 64-MSCT (distance between the CSO and the bottom floor of the right atrium). To our knowledge, this is the first prospective report using DS 64-MSCT and looking for anatomical factors impacting on CRT procedure parameters. Accordingly, non-invasive evaluation of the CSO position using DS 64-MSCT may predict a difficult CRT implantation procedure and this new information may help clinicians or manufacturers to improve LHDS material developments in the future.

**Potential risks related to cardiac resynchronization therapy procedure time and X-ray exposure**

Recently, CRT guidelines have been modified, extending the number of indications to LV dysfunction patients in NYHA Class II HF with LVEF ≤ 35% and QRS ≥ 150 ms under optimal medical treatment. As a result, the increasing number of indications for CRT over time has logically led to an increased number of device implantations. Yet, LV lead placement remains technically challenging and is considered to be the main factor impacting both procedure time and X-ray exposure. In the literature, only operator skills and experience were considered to play a predominant role on procedure duration. Based on their own experience, several authors have suggested that the successful outcome of LV lead placement might depend on CS anatomy, presence of the thebesian valve, stenosis, presence of tributary CS veins, and number of available veins. Previ-

**Factors affecting difficult cardiac resynchronization therapy implantation procedure**

Four studies examining the variables interfering with CRT procedure duration have been published, but their conclusions remain...
Macias et al. reported a survey involving 212 patients, 87.7% of which were successfully implanted with a mean procedure time of 120 min and mean X-ray exposure of 35.6 min. Two independent predictors of unsuccessful implantation were found: presence of chronic AF and left atrium dimensions. The major limitation of this study was its retrospective study design, as well as the inclusion of operator learning curves, along with the use of old design leads for guiding catheters and the inconsistency of the variable identified. Two studies have emphasized the impact of both operator experience and skills on the rate of primary CRT implantation success. This should encourage the development of centres of excellence, which is in line with the recently published paper by Freeman et al. regarding the relationship between hospital procedure volume and complications of ICD implantation. Regarding CRT implantation difficulties, the availability of venous anatomy should be required before CRT implantation, and previous multi-slice CT studies have underlined the variability of the CS tributaries. In a landmark study, the feasibility and reproducibility of 64-slice CT to depict CS anatomy was demonstrated in 100 patients referred for non-invasive angiography. Additionally, one recently randomized published study suggested that CT scan before CRT implantation may lead to decreased procedural times and fluoroscopy by helping operators to better prepare the CRT procedure. Indeed, implantation procedures are conventionally guided by the use of fluoroscopy, which offer a two-dimensional view of the vessel of interest. In this way, a more accurate interpretation of the anatomy allowing the appropriate

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Table 2 Comparison of patients’ characteristics according to prolonged (total procedure time ≥85 min) and non-prolonged procedure times

<table>
<thead>
<tr>
<th></th>
<th>Prolonged procedure time (n = 10)</th>
<th>Non-prolonged procedure time (n = 40)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>69.5 ± 11.2</td>
<td>69.2 ± 9.6</td>
<td>0.9</td>
</tr>
<tr>
<td>NYHA Class III</td>
<td>8</td>
<td>29</td>
<td>0.7</td>
</tr>
<tr>
<td>NYHA Class IV</td>
<td>2</td>
<td>11</td>
<td>0.7</td>
</tr>
<tr>
<td>BMI</td>
<td>27</td>
<td>28</td>
<td>0.8</td>
</tr>
<tr>
<td>Procedure time (skin to skin) (min)</td>
<td>114 min (50 min)</td>
<td>50.0 min (19 min)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total X-ray exposure (min)</td>
<td>49 min (46 min)</td>
<td>8.0 min (10 min)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total X-ray dose (Gy/cm²)</td>
<td>20 (22)</td>
<td>4.5 (6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LV lead X-ray time (min)</td>
<td>48 min (48)</td>
<td>6.3 min (9 min)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LV lead X-ray dose (Gy/cm²)</td>
<td>20 (21)</td>
<td>3.3 (6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AF</td>
<td>3/10 (30%)</td>
<td>7/40 (18%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Dilated cardiomyopathy</td>
<td>5/10 (50%)</td>
<td>23/40 (57.5%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Ischaemic cardiomyopathy</td>
<td>4/10 (40%)</td>
<td>14/40 (35%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Valvular cardiomyopathy</td>
<td>1/10 (10%)</td>
<td>3/40 (7.5%)</td>
<td>0.9</td>
</tr>
<tr>
<td>LVEF</td>
<td>28.5 ± 8</td>
<td>31 ± 7</td>
<td>0.4</td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>69 ± 12</td>
<td>65 ± 10</td>
<td>0.2</td>
</tr>
<tr>
<td>LVESD (mm)</td>
<td>60 ± 13</td>
<td>55 ± 11</td>
<td>0.15</td>
</tr>
<tr>
<td>LVEDV (mL)</td>
<td>159 ± 36</td>
<td>160 ± 60</td>
<td>0.9</td>
</tr>
<tr>
<td>LVESV (mL)</td>
<td>118 ± 38</td>
<td>116 ± 52</td>
<td>0.9</td>
</tr>
<tr>
<td>LAS (cm²)</td>
<td>27 ± 9</td>
<td>25 ± 7</td>
<td>0.5</td>
</tr>
<tr>
<td>TAPS right ventricle (mm)</td>
<td>17 ± 5</td>
<td>16 ± 5</td>
<td>0.6</td>
</tr>
<tr>
<td>Tortuous CS veins</td>
<td>2/10</td>
<td>10/40</td>
<td>0.5</td>
</tr>
<tr>
<td>LV position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral vein</td>
<td>6/10</td>
<td>31/40</td>
<td>0.6</td>
</tr>
<tr>
<td>PLV</td>
<td>2/10</td>
<td>8/40</td>
<td></td>
</tr>
<tr>
<td>Antero lateral vein</td>
<td>1/10</td>
<td>1/40</td>
<td></td>
</tr>
<tr>
<td>Posterior vein</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>CT scan RAS (cm²)</td>
<td>25 ± 8</td>
<td>27 ± 8</td>
<td>0.4</td>
</tr>
<tr>
<td>Number of available CS veins</td>
<td>4 ± 1.3</td>
<td>3.3 ± 0.7</td>
<td>0.3</td>
</tr>
<tr>
<td>CSO diameter (mm)</td>
<td>12 ± 3.6</td>
<td>11.7 ± 3.3</td>
<td>0.8</td>
</tr>
<tr>
<td>CSLI (mm)</td>
<td>14.8 ± 4</td>
<td>9.5 ± 4</td>
<td>0.01 *</td>
</tr>
</tbody>
</table>

LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; M-mode and bi-dimensional measurements were made according to the recommendations of the American Society of Echocardiography. LAS, left atrial surface; RAS, right atrial surface; CSLI, coronary sinus ostium-level insertion (the most sloping point of CSO and the tangent of the lower edge of the right atrium evaluated by DS 64-MSCT. 

*Median (interquartiles). 

P < 0.05.
material selection before starting the procedure may help to overcome these difficulties. Our study is the first prospective report using DS 64-MSCT and looking for anatomical factors influencing both CRT procedure and X-ray exposure times. Our survey emphasizes the key role of CSO-level insertion (evaluated by the most sloping point of CSO and the tangent of the lower edge of the right atrium), which may severely hamper access to the CSO or LV lead stability due to differences in anatomical landmarks. For example, both LV leads dislodgments and one failed LV lead implantation occurred in the group of difficult procedure with three patients whose CSO was located high (13, 13, and 20 mm, respectively). Interestingly, in the group of difficult procedure mainly due to CSO insertion, the operating time was twice greater and the amount of X-rays were six times greater compared with the other group. Conversely, when the junction between the CSO and the bottom floor of the right atrium is flat or short, the LHDS or the LV lead can slip directly inside the CSO without any difficulty. In the same manner, LV lead stability between both structures remains secure without traction strength on the LV lead due to a significant decline point. Other interesting information is the neutral role of right cavity dilatation, as we found that neither right atrium dilation nor right ventricular dysfunction nor tricuspid regurgitation grade were predictive of difficult CRT implantation procedures. Tortuous vessels or the number of CS side branches are common findings during CRT implantation, but these factors did not influence procedure times in our study. Accordingly, even if manufacturers have made several technical improvements to increase LV lead success rates, such as a variety of LHDS options as well as LV lead shapes and sizes, factors affecting procedure duration were unknown until now. Furthermore, our study confirmed that today, CRT procedures remain still difficult in 20% of cases. Thus, our study’s results may help new LHDS developments to overcome this peculiar difficulty.

Clinical implications

Implantation of special pacing leads for LV-based resynchronization therapy for congestive HF is a rather technical procedure, usually associated with high complication rates, including primary LV lead failure, prolonged CRT procedure time, prolonged X-ray exposure, LV lead dislodgment, and device-related infection. Preventing these complications and reducing X-ray exposure depend not only on operator skill and experience, but according to our study, CSO position also has a direct effect on CRT procedure. For some time, operators reported that CSO implantation level or shape could be responsible of LV lead instability or CS catheterization failure, but no clinical study examining right anatomical variables’ impact on CRT procedure, and particularly CS position had been carried out. In this clinical setting, we showed that DS 64-MSCT may help the operator in predicting difficult procedures, allow for improved evaluation of the material required prior to the procedure, and facilitate choosing a technical approach. This approach will be particularly useful in less skilled physician, helping them for better results of their procedures. Thus, a large curved guiding sheath should be pre-selected as well as a deflectable catheter with back bend moved into the CS. Moreover, alternative CRT implantation approaches may be discussed such as surgical epicardial lead implantation via minimally invasive alternatives or trans-atrial septum placements (via mitral valve). Additionally, this information may help manufacturers to develop a specific LHDS (steerable or not) dedicated to a CSO insertion located high.

Study limitations

The number of patients might have influenced the results, but on the other side the prospective design, as well as the blinded evaluation of CT scan parameters and the absence of interobserver variability emphasize the quality of these data. As not expected, right atrial dimensions and right ventricular dysfunction were not associated with prolonged procedure duration, primary LV lead implant failure, or LV lead dislodgments. On the other side, right cavity dimensions or surface measurements were evaluated using two methods, the TTE and DS 64-MSCT. We found similar results with both methods, and previous results argued for the absence of impact of these parameters. As operator experience might affect the results; only one very experienced operator (A.D.C.) was involved in this study in order to avoid bias in results as well as the same methodology of CRT procedure implantation. The availability or unavailability of certain implanting tools at the given centre and the experience of the single implanting physician in this study may explain why some factors that were shown to be associated with difficult LV lead placement previously were not found to be significant in this study. Consequently, the generalization of the results should be confirmed by other studies. There is no strong proof that identification of difficult cases would reduce implantation time/radiation dose in case a CT scan is performed on each patient before CRT implantation. Computed tomography scans pose a burden of additional radiation (0.35 Gy/cm²; 5.6 mSv). On the other side, operator X-ray exposure and implant time may possibly be reduced, with corresponding decrease in infectious risk. The CT scan may possibly be replaced by magnetic resonance imaging for routine pre-implant evaluation.

The absence of CS valves evaluation might have also influenced the study results.

Conclusions

Our study proved that despite improvements in the materials used, problems still remain in CRT procedure. In this clinical setting, the only predictive factor affecting CRT procedures duration and X-ray exposure is the CSO-level position (located high). This anatomical anomaly is responsible for 20% of difficult CRT device implantation procedures. Taking this anatomical parameter into account as evaluated by DS 64-MSCT prior to surgery may help both operators and/or manufacturers to develop new tools for this peculiar anatomy.

Conflict of interest: A.D.C. is a consultant for St. Jude Medical, Medtronic, Biotronik, and Boston Scientific, and has received research support from St. Jude Medical, Medtronic, Biotronik, Boston Scientific, and Sorin Group.

References


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14. Van de Veire NR, Schuijf JD, De Sutter J, Devos D, Bleeker GB, de Roos A
11. Knight BP, Desai A, Coman J, Faddis M, Yong P. Long-term retention of cardiac
12. Daoud EG, Kalbfleisch SJ, Hummel JD, Weiss R, Augustini RS, Duff SB. Implant-