# Success rate of transvenous left ventricular lead implantation for cardiac resynchronisation therapy — recent experience of a single centre

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## Abstract

**Background:** Implantation of a left ventricular (LV) lead for cardiac resynchronisation therapy (CRT) may be challenging. Wider use of various implantation techniques increases the success rate of CRT.

Aim: Short-term analysis of the success rate of transvenous LV lead implantation for CRT.

**Methods:** All CRT procedures performed in 2009 with first-time LV lead implantation attempt were analysed in terms of efficacy, total number of procedures, procedure and fluoroscopy time, complications, and reinterventions. Final LV lead location and the number of tested sites were analysed. Complex procedures were defined and described.

**Results:** We studied 122 patients aged 67.6  $\pm$  10.6 years (98 males/80%) selected for CRT. The CRT implantation was an upgrade procedure in 17 patients. Fifty-six (46%) patients had coronary artery disease and 111 (91%) patients were in NYHA class III. The mean LV ejection fraction was 27% (range 10–35%). The implantation success rate was 97.5%. There were 87 (73%) CRT-D systems implanted and 32 (27%) CRT-P systems. Mean procedure time was 118  $\pm$  41 min, and fluoroscopy time was 15.9  $\pm$  12.1 min. An optimal location of the LV lead was achieved in 107 (90%) patients. More than one LV lead sites were tested in 42 (35.3%) patients. Complex procedures were performed in 4 (3.4%) patients. Early LV lead reintervention (< 30 days) was necessary in 10 (8.4%) patients (11 procedures), and epicardial lead placement was performed in one patient. The LV lead location in the antero-lateral branch demonstrated the lowest reintervention rate (1/22, 4.5%) vs other sites (great cardiac vein: 1/8, 12.5%, lateral branches: 9/86, 10.5%, p = NS). The LV lead-related reinterventions and initial procedure failure were associated with the upgrade procedures. No serious periprocedural complications were recorded. In one patient, the CRT system was explanted due to pocket infection. One patent died three months after CRT implantation due to progressive end-stage congestive heart failure.

**Conclusions:** 1. In a tertiary centre, CRT implantation success rate is high and implantation procedures are safe. 2. Achieved LV lead location is optimal in a vast majority of patients. 3. We noted a significant rate of early reinterventions related to LV lead dislodgement. 4. The LV lead implantation failure and reinterventions occurred more frequently in subjects with upgrade-to-CRT procedures. A similar trend was also noted in patients after cardiac surgery. 5. In selected cases, advanced techniques must be used to achieve successful CRT implantation.

Key words: cardiac resynchronisation, left ventricular lead implantation, reinterventions, cardiac vein reopening

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# INTRODUCTION

With a wider use of cardiac resynchronisation therapy (CRT), the success rate of CRT device implantation continues to increase [1]. In addition to improvement in dedicated devices and increased operator experience, this has also resulted from adapting invasive cardiology techniques for the use within cardiac veins. A number of specific auxiliary indirect methods were also developed. In this report, we present the efficacy of CRT device implantation procedures and the spectrum of interventional procedures used to achieve successful CRT in

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patients with congestive heart failure (CHF) treated in our tertiary cardiac electrotherapy centre during the last year.

The aim of the study was a short-term analysis of the efficacy of transvenous left ventricular (LV) lead implantation for CRT accounting for the complexity of interventional procedures.

### **METHODS**

We analysed all first-time LV lead implantations for CRT performed in our department in 2009. This was the ninth calendar year of the use of this method in our centre. All patients were selected for the procedure according to the current European Society of Cardiology guidelines [2].

#### Implantation procedure

The pacing-only devices (CRT-P) were implanted under local anaesthesia, while CRT systems with defibrillator capability (CRT-D) were implanted under general anaesthesia. The procedure began with percutaneous puncture of the left subclavian vein (LSV). Using this approach, a coronary sinus (CS) catheterisation system was introduced. The CS bed was then opacified directly through the catheter or with the use of a balloon catheter in at least two views (anteroposterior and left oblique at 30-45°) to delineate anatomy and identify potential target coronary vein. After the LV lead type was selected (at least two types were always available), we attempted to place it in the final destination and confirm acceptable electrical stimulation parameters. If the initial attempt failed, we tried to implant the LV lead to some other side branch. Right atrial and right ventricular leads were routinely implanted subsequently using the left cubital vein or LSV approach. The order of lead implantation could have been reversed at the operator discretion in case of high degree atrioventricular (AV) conduction disturbances. All procedures were performed by 4 operators, including 2 with overall experience of > 400procedures and the remaining 2 with the experience of < 20procedures per person.

#### Analysed parameters

We evaluated final efficacy of the primary procedure, total number of procedures, procedure and fluoroscopy time, complications, and reinterventions related to the LV lead. Final lead location was defined as optimal if within the lateral wall (including posterior lateral vein [PLV], lateral vein [LV], posterior vein [PV], anterior lateral vein [ALV], and lateral branches of other veins) or suboptimal in the remaining positions (greater cardiac vein [GCV] and intermediate vein [IMV]). We also analysed the number of tested LV sites before reaching the final lead location, causes of intraprocedural repositions, and causes of early postprocedural reinterventions (within 30 days).

We also performed separate analyses of procedures in which initial tested LV site was also the final one (group A), procedures with at least two tested LV sites (group B), and complex procedures defined as > 1 procedural session or

the use of non-standard techniques and equipment (the standard equipment included a CS catheterisation system, an electrophysiological electrode or angiography catheter as the guiding catheter, a balloon catheter to opacify CS, one electrode, and a 0.014" guidewire).

#### Statistical analysis

The results are presented as mean  $\pm$  SD or numbers and percentages. The student t-test or  $\chi^2$  test were used to asses differences between analysed parameters where appropriate. A p value < 0.05 was significant.

## RESULTS

During the analysed calendar year, 122 patients aged 67.6  $\pm$  10.6 years, including 98 (80%) men, were referred for the first-time CRT system implantation in our centre. The CHF was secondary to coronary artery disease (CAD) in 56 (46%) patients, and non-CAD aetiology of CHF was found in 66 (54.1%) patients, including 50 men and 16 women. The NYHA class III symptoms were present at baseline in 111 (91%) patients, and the mean LV ejection fraction was 27% (range 10–35%).

The study group included 17 patients with previously implanted conventional pacemaker or cardioverter-defibrillator (ICD) system that was upgraded to CRT, including single-chamber atrial pacemaker in 1 patient, single-chamber ventricular pacemaker in 7 patients, dual chamber AV pacemaker in 7 patients, and ICD with dual chamber AV pacing capability in 2 patients. In addition to 17 LV leads, 14 other leads were implanted in these groups.

Primary implantation using the transvenous approach was successful in 119 (97.5%) patients who underwent overall 120 procedures. We implanted 87 (73.1%) CRT-D systems and 32 (26.9%) CRT-P systems. In 2 men (both with NYHA class IV symptoms at baseline), CRT-P with two-site LV stimulation (TriV) were implanted. The mean duration of procedure was 118  $\pm$  41 min, and the mean fluoroscopy time was 15.9  $\pm$  12.1 min. The LV lead location was considered anatomically optimal in 107 (89.9%) patients and suboptimal in 12 (10.1%) patients.

Detailed outcomes in the analysed patient subgroups depending on the procedure type are shown in Table 1. Causes of failed procedures in 3 (2.5%) patients included lack of appropriately sized lateral branches for the LV lead, high pacing threshold or diaphragm pacing in all available and tested sites, and inability to intubate the CS ostium.

Subsequent to initially successful CRT pacing, an early reintervention ( $\leq$  30 days) related to the LV lead was necessary in 10 (8.4%) patients (11 procedures) (Table 2). In 1 patient in this group, dislocation occurred twice and the patient was finally referred for cardiac surgery with epicardial lead placement through lateral thoracotomy approach. The indications for reintervention included total displacement of the LV lead out of a lateral branch in 2 cases, phre-

	Group A	Group B	Group C	Р
N (%)	73 (61.3%)	42 (35.3%)	4 (3.4%)	Not applicable
Coronary artery disease	34 (46.6%)	19 (45.2%)	0	NS
Procedure time [min]	$109\pm31$	$126\pm35$	221 ± 94	A vs C, B vs C < 0.0001
Fluoroscopy time [min]	$13.3\pm8.8$	$17.1\pm9.0$	$45.3\pm37.5$	A vs C, B vs C < 0.0001
Optimal lead position	71 (97.3%)	32 (76.2%)	4 (100%)	B vs A, B vs C < 0.0001
Number of tested LV lead sites per procedure	1	2.3 (2–4)	1	Not applicable
Left ventricular lead pacing threshold [V]	$1.7\pm0.9$	$1.9 \pm 1.0$	$2.2 \pm 1.1$	NS
Previous cardiac surgery	8 (11.0%)	3 (7.1%)	1 (25%)	NS
Upgrade of previously implanted pacemaker	12 (16.4%)	11 (26.2%)	2 (50%)	NS
Previous cardiac surgery or pacemaker implantation	19 (26.0%)	13 (31.0%)	2 (50%)	NS

Table 1. Comparison of clinical data and procedural details between analysed groups

Group A — first tested LV site was the final one; group B — at least two tested LV sites; group C — complex procedures

Table 2. Details of early left ventricular lead reintervention procedures (< 30 days)

Reintervention	N (overall)	B	Baseline group		
		A	В	С	
Lead reposition within the same side branch	4	3	1	_	
Lead reposition to another side branch	6	3	3	_	
Optimal → suboptimal	3	3	-	-	
Optimal → optimal	2	_	2	-	
Suboptimal → optimal	1	_	1	-	
Lead replacement within the same side branch	1	-	1	-	

Table 3.	Outcomes in	relation to	previous	cardiac surgery	and	previously	implanted	pacemaker	upgrade	procedures

	1. Previous cardiac surgery		2. Previous pacemaker		1 (	1 or 2		
			implantati	on (upgrade)				
	Yes (n = 13)	No (n = 109)	Yes (n = 28)	No (n = 94)	Yes	No		
Successful procedure without early LV lead reintervention	9 (69.2%)	99 (90.8%)	22 (78.6%)	86 (91.5%)	30 (81.1%)	78 (92.8%)		
Successful procedure with early LV lead reintervention	3 (23.1%)	8 (7.3%)	3 (10.7%)	8 (8.5%)	4 (10.8%)	7 (8.2%)		
Unsuccessful procedure	1 (7.7%)	2 (1.3%)	3 (10.7%)	0	3 (8.1%)	0		
	p = 0.0643 (NS)		p = 0	.0120	p =	p = 0.0323		

LV — left ventricular

nic nerve stimulation in 3 cases, and lead dislocation with an increase of pacing threshold above the pacing safety margin in 6 cases. In 10 cases, reintervention included reposition of the previously inserted lead, and in one case, new lead with active sinus fixation was implanted (Attain StarFix<sup>®</sup> Model 4195 OTW, Medtronic, Minneapolis, MN, USA). Reinterventions were only necessary in groups A and B, more commonly in the latter group (group A 6/73 patients, 8.2% vs group B 5/42 patients, 11.9%, NS). Initial LV lead location within ALV was associated with the lowest rate of reinterventions (1/22 patients, 4.5%) compared to all other initial locations (GCV: 1/8 patients, 12.5%, PLV/PV: 9/86 patients, 10.5%, NS) but these differences were not significant.

The necessity of reintervention to relocate the LV lead and unsuccessful attempts of CRT system implantation were significantly more common in patients with upgrade procedures. Similar trend regarding both these clinical situations was also seen in patients who underwent cardiac surgery prior to the CRT system implantation (Table 3).



**Figure 1.** A complex procedure of CRT-D system implantation in a 61 year-old female patient. **A.** A tortuous posterior lateral vein seen in an left oblique view at 30°; **B.** Selective cannulation of the side branch using Attain Select<sup>®</sup> II catheter (Medtronic, Minneapolis, MN, USA), anteroposterior view; **C.** Selectively inserted lead in its final position, anteroposterior view



**Figure 2.** A complex procedure of CRT-D system implantation in a 64 year-old female patient. **A.** Lateral vein stenosis, anteroposterior view; **B.** Selectively inserted lead in its final position, with the initial lead replaced with a QuickFlex<sup>TM</sup>  $\mu$  lead (4.0 F tip/4.3 F bulk, St. Jude Medical, St. Paul, MN, USA), anteroposterior view (due to concomitant persistent second degree atrioventricular block, coronary sinus catheterisation was preceded by right ventricular and right atrial lead implantation)

We noted no major complications of primary procedures and reinterventions. A minor CS dissection was seen intraprocedurally in 4 (3.4%) patients (3% procedures), requiring no intervention and allowing continuation of the procedure. In 1 patient who underwent reintervention for lead dislocation, the CRT system was explanted due to pocket infection. One patient with a TriV system died 3 months after CRT implantation due to progressive end-stage CHF.

Complex procedures were performed in 4 (3.4%) patients and included:

- LV lead implantation via an atypical venous return to distal CS and ALV with occluded CS ostium at the right atrium.
- The use of subselective leading catheter Attain Select<sup>®</sup> II (Medtronic, Minneapolis, MN, USA) to pass a venous siphon at the ostium of PLV (Fig. 1).

- The use of QuickFlex<sup>TM</sup> μ lead (4.0 F tip/4.3 F bulk, St. Jude Medical, St. Paul, MN, USA) instead of a larger lead used initially, to be inserted into a stenosed lateral branch (Fig. 2).
- Recanalisation of the passage between CS and GCV using a 0.014" guidewire and Attain 6215-80 balloon catheter (Medtronic, Minneapolis, MN, USA), followed by LV lead implantation to ALV. The procedure was performed at the second session (Fig. 3).

## DISCUSSION

The success rate of transvenous CRT system implantation in our 122 (97.5%) patients was high and consistent with the current expectations of tertiary referral centres. Thus, near 100% success rate is possible with the use of very advanced vascular access techniques in difficult cases [3]. In our study



**Figure 3**. A complex procedure involving an upgrade of a VVI pacemaker to a CRT system (second session) in a 78 year-old male patient. **A**. An occluded passage between the coronary sinus and the greater cardiac vein (circle), anteroposterior view. **B**. A lead inserted to its final position in the anterior lateral vein following recanalisation of the passage, anteroposterior view

group, 120 procedures were performed, with only 1 patient requiring two intervention sessions.

The LV lead instability is a major adverse event during CRT, sometimes with grave clinical consequences, such as acute CHF decompensation in responders, or proarrhythmia [4]. In our study group, macro- and microdislodgement with loss of effective pacing or diaphragm stimulation were insignificantly more common in patients requiring testing of several LV lead sites during the initial procedure, and did not occur in patients who underwent complex procedures. In some cases of the LV lead instability, the use of an active sinus fixation lead or lead stenting within a vein may be helpful [5]. However, despite initial success, both these techniques are used cautiously due to uncertain long-term outcomes [4].

Although current findings suggest that the distinction between optimal and suboptimal LV position has become less important, we still try to insert the LV lead close to the lateral or posterior LV wall [6, 7]. In our patients, such location was achieved in nearly 90% of cases, including more than 97% cases with acceptable initial tested location and all patients undergoing complex procedures. The course of GCV and IMV in the anterior and posterior interventricular groove results, if the lead is not placed in posterior or lateral branches of these veins, in resynchronisation pacing from the distal vessel segments that is similar to two-site right ventricular pacing, considered inferior to CRT. In our study population, the LV lead was finally placed in GCV in only 8 cases, and in only 1 patient in group A. At the same time, our findings suggest that implantation of the LV lead into ALV, a side branch of GCV that leads to an anatomically optimal region of free LV wall, was associated with the lowest rate of reinterventions during a short-term follow-up. This was likely related to more lead turns within the coronary venous bed, providing more friction and stability, and a more remote location in

regard to the left phrenic nerve. Of note, such benefits were not seen despite similar course of the LV lead inserted into GCV itself. Reintervention rate was also higher following procedures in which the final lead location was not the initially tested one. In such situations, some trade-off is usually necessary, resulting in potentially lower safety margin.

If the transvenous approach is unavailable or fails, epicardial LV lead placement is an alternative solution for patients that might benefit most from CRT, with hybrid approach that also involves transvenous insertion of the right atrial and right ventricular leads. For the cardiac surgeon, these procedures pose relatively little difficulty but there is some risk related to thoracotomy and general anaesthesia in patients with advanced CHF [8]. This strategy should not be used liberally but reserved for selected patients with indications for CRT, and recommended as the treatment of choice in patients with indications for CRT who undergo elective cardiac surgical procedures [9]. In our study group, we used the epicardial approach in one patient following recurrent LV lead dislodgement from the only available short venous side branch.

The CS ostium at the right atrium may be occluded [10], and after the initial diagnosis of 2 operators we retrospectively confirmed such occurrence with CT scanning in 1 patient in group C. This patient had the LV lead implanted through a persistent left superior vena cava draining into CS. In case of difficult or unsuccessful procedures, careful consideration of the benefit to risk ratio with continuation of the procedure or repeated attempt is necessary, sometimes leading to reconsideration of indications for CRT [11, 12]. We did not see any major intraprocedural complication in our patients, with minor CS dissection in 4 patients that allowed continuation of the procedure and did not result in any sequelae. The single instance of early pocket infection is a complication that has been reported in the literature, and the single death of a patient with end-stage CHF despite the use of TriV pacing resulted from the natural history of the disease [13].

An occlusion or a significant narrowing of one cardiac vein is a common occurrence, while occlusion of CS or several major veins is rarely noted. In the latter cases, collateral circulation usually develops, but the diameter of these vessels does not allow insertion and stable positioning of even the smallest LV leads. In 1 patient, we decided to cross an occluded passage between CS and GCV, searching for anterolateral branches of the latter vessel. If unsuccessful, we contemplated recanalisation of a narrow PLV that was occluded proximally. Due to severe CHF with NYHA class IV symptoms and concomitant disease, epicardial lead placement via thoracotomy approach was not considered suitable in that patient.

The pathomechanism of venous stenoses and occlusions is different than in the arterial circulation. Thus, "arterial" interventional techniques often do not have to be fully adapted in such cases [14]. In one of our patients, stabilisation of a 0.014" guidewire proved sufficient to recanalyse the occlusion (most likely due to an organised thrombus) by crossing it with a balloon catheter normally used for CS cannulation and opacification, without the use of a standard balloon catheter. The key aspect in regard to the safety of this procedure was the confirmation of the presence of the 0.014" guidewire within the venous bed distally to the occlusion. In group C patients, in whom narrowed lateral branch was crossed with the thinnest available leads or a venous siphon was passed with a subselective leading catheter, such approaches may be considered alternative to venous angioplasty [15].

The authors routinely perform subclavian vein puncture to insert the LV lead system prior to skin incision. This strategy seems to be justified by only very rare cases of an immediate failure of such an approach.

# **CONCLUSIONS**

- In a tertiary centre, primary CRT implantation success rate is high, with low rate of periprocedural complications.
- Achieved LV lead location is anatomically optimal in most cases.
- 3. The CRT system implantation is associated with a high rate of early lead dislocation or diaphragm stimulation requiring reinterventions for LV lead reposition.
- The LV lead implantation failure and reinterventions occurred more frequently in subjects undergoing upgrade

procedures. A similar nonsignificant trend was also noted in patients after cardiac surgery.

 In selected cases, advanced techniques must be used to achieve successful CRT implantation.

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# Przezżylny dostęp dla elektrody lewokomorowej — techniki zabiegowe i bezpośrednia skuteczność wszczepień układów resynchronizujących w ostatnim roku doświadczeń ośrodka

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# Streszczenie

Wstęp: Wraz z powszechniejszym zastosowaniem terapii resynchronizującej (CRT) zwiększa się skuteczność zabiegów.

Cel: Celem pracy była obserwacyjna analiza krótkoterminowa skuteczności uzyskania stymulacji lewokomorowej (LV) dla CRT.

**Metody:** Analizie poddano zabiegi implantacji układów do CRT z pierwszorazowym wszczepieniem elektrody LV, przeprowadzone w 2009 roku. Oceniano: ostateczną skuteczność pierwotnego zabiegu, liczbę sesji zabiegowych, czas zabiegu, skopii RTG, powikłania i reoperacje związane z elektrodą LV. Oceniano położenie elektrody: optymalne lub suboptymalne, liczbę testowanych położeń elektrody LV oraz wyodrębniono grupę zabiegów technicznie złożonych.

Wyniki: Do CRT w 2009 roku zakwalifikowano 122 osoby w wieku 67,6 ± 10,6 roku, 98 (80,3%) mężczyzn i 24 (19,7%) kobiety. U 17 osób rozbudowano układ do CRT. U 56 (45,9%, 48M/8K) osób niewydolność serca wiązała się z chorobą wieńcową (CAD); u 66 osób (54,1% 50M/16K) etiologia niewydolności serca była pozawieńcowa (non-CAD). Wyjściowo w klasie III wg NYHA było 111 chorych (91%), LVEF wynosiła średnio 27% (10-35%). Skuteczne wszczepienie uzyskano u 119 (97,5%) osób w wyniku 120 zabiegów. Wszczepiono 87 (73,1%) układów CRT z funkcją defibrylacji i 32 (26,9%) z funkcją stymulacji (CRT-P). U 2 chorych (2M, obaj wyjściowo w IV klasie wg NYHA) wszczepiono układy CRT-P z dwupunktową stymulacją LV (TriV). Czas trwania zabiegu wynosił średnio 118 ± 41 min, a czas fluoroskopii 15,9 ± 12,1 min. Położenie elektrody LV zdefiniowane jako anatomicznie optymalne uzyskano u 107 (89,9%) osób, położenie suboptymalne u 12 (10,1%) pacjentów. U 42 (35,3%) chorych ostateczne położenie elektrody LV było kolejnym testowanym miejscem. Zabiegi złożone wykonano u 4 (3,4%) osób. Były to: wszczepienie elektrody LV przez atypowy spływ żylny, wykorzystanie subselektywnego cewnika prowadzącego, zastosowanie elektrody o średnicy 4,0/4,3 F w celu wprowadzenia do przewężonej żyły bocznej i udrożnienie przejścia do żyły wielkiej serca. Wczesna reinterwencja (< 30 dni) w zakresie elektrody LV była konieczna w 11 przypadkach u 10 (8,4%) chorych. Jednego pacjenta zakwalifikowano ostatecznie do zabiegu kardiochirurgicznego naszycia elektrody LV. Reoperacje nie wystąpiły w grupie zabiegów złożonych. Wyjściowe położenie elektrody w żyle przednio-bocznej wiązało się z trendem do najmniejszego bezwzględnego odsetka wczesnych reinterwencji (1/22; 4,5%), w porównaniu z pozostałymi wyjściowymi lokalizacjami (żyła wielka: 1/8, 12,5%; żyły boczne i tylno-boczne: 9/86; 10,5%, NS). Konieczność rewizji elektrody LV i nieskuteczność prób wszczepień układów do CRT były statystycznie częstsze u chorych z rozbudową układów. Nie zanotowano poważnych śródzabiegowych powikłań zabiegów pierwotnych i reoperacji. U 1 chorego układ usunięto w całości z powodu infekcji loży. Jeden chory z układem TriV zmarł 3 miesiące po zabiegu w wyniku progresji niewydolności serca.

Wnioski: 1. Bezpośrednia skuteczność zabiegów wszczepienia układów do terapii resynchronizującej w ośrodku referencyjnym jest wysoka, przy małym odsetku powikłań okołozabiegowych. 2. W większości przypadków uzyskuje się miejsce stymulacji LV oceniane jako anatomicznie optymalne. 3. Terapia resynchronizująca wiąże się z dużym odsetkiem: wczesnych dyslokacji lub stymulacji przepony, wymagających operacyjnej rewizji elektrody LV. 4. Nieskuteczność zabiegów i wskazania do wczesnej rewizji elektrody LV występowały częściej, po rozbudowie wszczepionych uprzednio urządzeń. Tendencja taka pojawiła się również u chorych po przebytych zabiegach kardiochirurgicznych. 5. W wybranych przypadkach konieczne jest zastosowanie zaawansowanych technik naczyniowych, cechujących się dużą skutecznością.

Słowa kluczowe: terapia resynchronizująca, przezżylne wszczepienie elektrody LV, reoperacje, udrożnienie żyły serca Kardiol Pol 2010; 68, 8: 903–909

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