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Cardiac resynchronization therapy after coronary sinus lead extraction: feasibility and mid-term outcome of transvenous reimplantation in a tertiary referral centre

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Aims Few data are available on cardiac resynchronization therapy (CRT) after coronary sinus (CS) lead extraction. We aimed to evaluate the feasibility and mid-term outcome of transvenous CS lead reimplantation in a tertiary referral centre.

Methods and results We enrolled all patients who were referred to our hospital for CS lead removal from December 2000 through to May 2009 and were transvenously reimplanted with a CRT system before June 2009. One-year follow-up was performed to evaluate the incidence of infections, malfunctions, and mortality. We studied 113 consecutive patients undergoing successful CS lead extraction; 90 patients (75 male, mean age 69.2, range 35–84) underwent CS lead reimplantation (success rate: 95.6%; right-sided approach: 64.4%). In these patients, cardiac device infection was the usual indication for extraction (74.4%) and the subsequent reimplantation was performed after a median time of 3 days. The coronary sinus lead was usually positioned in the left ventricular (LV) postero-lateral region (62.2%); two procedures were required in two cases (2.2%). Balloon angioplasty was necessary for two patients (failure in one), whereas for the others we used a conventional implant technique. During follow-up, we observed four cases (4.4%) of local infection and six cases (6.7%) of system malfunction, requiring reintervention (two cases during the same hospitalization). One-year mortality was 5.5%.

Conclusion Left ventricular lead reimplantation is in our experience an effective and safe procedure, also in the case of right-sided approach. During follow-up, 1-year mortality was particularly low, whereas overall infection rate was higher than first implant procedures.

Keywords Cardiac resynchronization therapy • Lead extraction • Cardiac device infection • Pacemaker reimplantation • Pacemaker complication

Introduction

In the era of cardiac resynchronization therapy (CRT), a new and interesting field has developed relating to left ventricular (LV) pacing lead extraction and subsequent reimplantation. Although extensive data are available on conventional pacing and defibrillating lead extraction, only limited experience with LV leads has been reported.[1–4] The LV pacing leads may be removed easily by manual traction in a large number of cases, but coronary sinus (CS) adherences may sometimes complicate extraction requiring mechanical dilation or ablative extraction techniques.[5] In addition to CS remnant adherences, post-extraction venous occlusion

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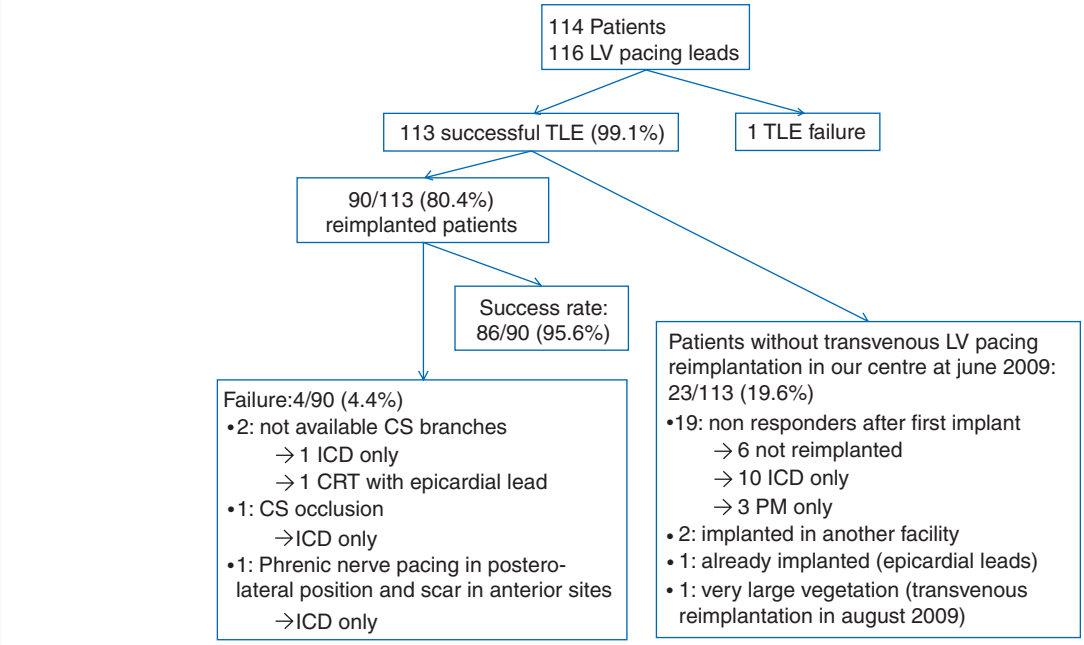

Figure 1 Population study, from lead extraction to reimplantation. CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; PM, pacemaker; TLE, transvenous lead extraction.

might complicate the eventual reimplantation.[3] Few data are available on the feasibility and outcome of CS lead reimplantation after a previous CRT device removal. Some authors described a poor outcome, mainly related to an occlusion of the CS or target branches.[3] The transvenous reimplantation can be challenging in some cases and specific tools, used commonly by interventional cardiologists, could be necessary to perform a successful resynchronization. The aim of this study was to evaluate the effectiveness, feasibility, and mid-term outcome of transvenous LV pacing lead reimplantation in patients previously treated with CRT device removal and CS lead extraction.

Methods

Population study

We included in our study all the consecutive patients, who underwent LV pacing lead removal between January 2000 and May 2009 and were transvenously reimplanted with a CRT system in our centre before June 2009 (*Figure 1*). These cases were identified using a computerized database, where patient's baseline data were collected case-by-case and retrospectively analysed. Considering CS lead removal indication, the overall population was divided into *malfunction* and *infection groups*. One-year follow-up was performed to evaluate the incidence of infections, malfunctions, and mortality.

Lead extraction procedure

The lead extraction technique that we used was recently described.[5,6] Briefly, the procedures were usually performed under local anaesthesia or sedation using intravenous propofol and remifentanyl. Arterial blood pressure was monitored via an arterial line placed in the left radial artery; a temporary pacemaker was placed in the right ventricle, through a 6 Fr introducer positioned in the left femoral vein. Electrocardiographic and oxygen saturation monitoring was done. After device removal, leads were examined visually and by fluoroscopy in their intravascular segment; the proximal end was clipped and a standard stylet was introduced. Lead extraction was then attempted using a gentle manual traction. When it was unsuccessful, we used a modified Byrd technique[6] with a superior approach, and we performed a mechanical dilatation of the adherences using a specific extraction kit (Cook Intravascular Inc., Leechburg, PA, USA). Alternatively, when the LV pacing leads were intravascular and free-floating or the removal through the implant vein was not possible, we performed a femoral vein approach; if necessary, we used additional intravascular tools (Catchers and Lassos, Osypka, Grentzig-Whylen, G; Tip Deflecting Wire, Cook Intravascular Inc., Leechburg, PA, USA). We used neither powered sheaths (i.e. laser or radiofrequency) nor rotating threaded tip sheaths (Cook Vascular Evolution). Removing infected pacing/defibrillating leads was done after at least 2 weeks of antibiotic therapy; particular attention was dedicated to patients with endocarditis, in whom >3 weeks of preoperative antibiotics therapy was considered necessary for safe extraction and reimplantation.[7]

Lead reimplantation technique

The need for CRT in patients undergoing CS lead extraction was always reassessed after lead removal; particularly, non-responder patients were still considered eligible for reimplantation if the previous LV pacing site was inappropriate (i.e. anterior sites) or those patients were pacemaker dependent. We usually store the radiological positions of leads before the extraction for an accurate leads visualization and *post-hoc* strategy delineation. According to our general practice, in the malfunction group the CRT was performed immediately after the extraction procedure, whereas in the infection group it was performed at least 48 h later. In the former group, the entry site did not change

after lead extraction and the polypropylene sheath was often used to advance the guidewire in the right atrium; in the latter group, reimplantation was usually performed in the contralateral site. Before LV lead reimplantation, all patients underwent CS venography. The images were taken from the postero-anterior, right anterior oblique, and left anterior oblique views and subsequently stored in an archive. In this way, the patency of the venous system was evaluated in order to decide which branch to use for reimplantation. We calculated the procedural and fluoroscopy times; they did not include the extraction time in the case of single-day procedure (malfunction group). In the case of implantable cardioverter defibrillator (ICD) reimplantation, we performed the defibrillation testing in all but patients with very low ejection fraction (i.e. <20%) or with left-sided chambers thrombosis.

Antibiotic treatment was used as prophylactic therapy in case of reimplantation due to malfunction, whereas it has been continued for at least 2 weeks in case of local infection, and for more than 4 weeks in case of endocarditis or systemic bacteraemia.[8] In the infection group, the therapy was based on the results of the blood and tip cultures; local infectious diseases specialist was usually contacted to decide the correct treatment. Typically, we used an antibiotic combination and patients were discharged when intravenous administration was replaced by the oral one. When there was neither growth in blood/tip cultures, nor previously documented isolation, we have administered an empiric therapy.[9]

Statistical analysis

Results are presented as mean ± standard deviation, median with range (or 25–75° percentile) or frequencies of patients. Parametric continuous variables were evaluated using the unpaired *t*-test. Non-parametric continuous variables were evaluated using the Mann–Whitney *U*-test. Pearson χ^2 test was used for the categorical variables. Statistical significance was defined at $P < 0.05$.

Results

Population study

The LV pacing lead reimplantation was performed in 90 out of 113 patients (80.4%), who underwent successful CS lead removal (*Figure 1*). Nineteen non-responder patients after first implant were not considered eligible to LV pacing lead reimplantation: 6 patients were not reimplanted with any devices, whereas 13 patients underwent pacemaker or ICD implant without biventricular pacing. Four patients were not included in the population study, despite being considered CRT responders: two of them were reimplanted in different hospitals, one patient had already been reimplanted with an epicardial lead before the extraction and one patient, admitted for a very large lead-related vegetation precluding early reimplantation, was reimplanted after the end of the enrolment (August 2009). The number of procedures increased dramatically over time, even though in the first 3 years only one out of eight patients underwent reimplantation. The baseline characteristics of reimplanted population are shown in *Table 1*.

Coronary sinus lead reimplantation procedural outcome

The CS lead reimplantation was successful in 86 out of 90 patients (95.6%), but two procedures were required in 2 patients belonging

Table 1 Baseline characteristics of patients undergoing cardiac resynchronization therapy after transvenous lead extraction/removal

Patients	90
Sex (male)	75/90 (83.3%)
Age, years	69.2 ± 10.4 (35–84)
Clinical history	
Ischemic aetiology	45/90 (50%)
Diabetes	21/90 (23.3%)
Hypertension	47/90 (52.2%)
Chronic obstructive pulmonary disease	17/90 (18.9%)
Chronic renal insufficiency	34/90 (37.8%)
Prior cardiac surgery	27/90 (30%)
New York Heart Association functional class	2.7 ± 0.7
LV ejection fraction	29.3 ± 8.7
Transvenous lead extraction data	
Time between first implant and lead extraction (months) [Median (25°–75° percentile)]	21.5 (10–42)
Infection indication for lead extraction	67/90 (74.4%)
Local infection	49/90 (54.4%)
Systemic infection	18/90 (20%)
Device removed (ICD)	75/90 (83.3%)
Leads removed per patient [Median (range)]	3 (1–6)
Techniques for lead extraction	
Mechanical dilatation (LV)	22/90 (24.4%)
Transfemoral approach (LV)	4/90 (4.4%)
Mechanical dilatation (RV)	86/96 (89.6%)
Mechanical dilatation (RA)	53/76 (69.7%)
Reimplanted devices/leads data	
Devices	
ICD	76/90 (84.4%)
Pacemaker	14/90 (15.6%)
Leads	
Saint Jude Medical	68/90 (75.6%)
1055K	3/90
1056K	4/90
1056T	54/90
1058T	1/90
1156K	1/90
1156T	5/90
Guidant	20/90 (22.2%)
4517	20/90
Medtronic	1/90 (1.1%)
4194	1/90
Ela Medical	1/90 (1.1%)
UW 28D	1/90

ICD, implantable cardioverter defibrillator; LV, left ventricular; RV, right ventricular; RA right atrial.

Table 2 Reimplantation procedure data and perioperative outcomes

	Malfunction group ($n = 23$)	Infection group ($n = 67$)	Overall ($n = 90$)
Reimplantation success rate	21/23 (91.3%)	65/67 (97%)	86/90 (95.6%)
LV postero-lateral implant	13/23 (56.5%)	43/67 (64.2%)	56/90 (62.2%)
Right sided Reimplantation	None	58/67 (86.6%)*	58/90 (64.4%)
Ipsilateral Reimplantation	23/23 (100%) • Right side None • Left side 23/23 (100%)	5/67 (7.5%)* • Right side None • Left side 5/67 (7.5%)	28/90 (31.1%) • Right side None • Left side 28/90 (31.1%)
Time between extraction and reimplantation (days)			
Median (25–75° percentile)	0	3 (2–4)*	2 (1–4)
Fluoroscopy time (min)	39.8 ± 39.9	38.1 ± 17.5	38.5 ± 25.2
Procedural time (min)	116.5 ± 65.8	143 ± 39.2	136.1 ± 48.6
Acute perioperative complications	2 pocket haematoma not requiring evacuation (8.3%)	None	2 pocket haematoma not requiring evacuation (2.2%)
In-hospital deaths	None	1/67 (1.5%)	1/90 (1.1%)

In patients undergoing lead extraction for systemic infection the median time to reimplant was 3 days (25–75° percentile: 2–5), whereas the mean time was 9.8 ± 18.7 days.
LV, left ventricular.
*$P < 0.000001$, °$P < 0.05$ malfunctioning vs. infection group.

to the infection group (2.2%) (*Table 2*). The unsuccessful attempts were due to the lack of available branches (occlusion) in two cases, CS occlusion in one patient and CS branches not suitable because of phrenic nerve pacing or high threshold in one patient. One patient without available branches was referred to the surgeon in order to perform an epicardial LV pacing lead implant; he died suddenly of a stroke 3 days after the procedure and was the only in-hospital death observed in our population (1.1%). The other three patients refused the epicardial approach and underwent ICD implant without biventricular pacing (*Figure 1*). The LV pacing lead was more frequently positioned in the postero-lateral region than in the anterior or septal sites (62.2 vs. 37.8%). The reimplantation was usually performed in the right side in the infection group (86.6%), whereas it was always in the left side (ipsilateral to first implant) in the malfunction group. An ipsilateral reimplantation was considered only in very selected cases in the former group.

Conventional techniques for reimplantation were usually adopted, with the exception of two patients who required a balloon angioplasty to carry out the implant. In the former case, the angioplasty did not allow crossing stenosis of the CS branch where the old lead was previously placed, so we placed the new CS lead in the antero-lateral LV region. The angioplasty was successfully performed two times in the latter patient.[10] The venography documented a significant stenosis at the middle part of the main CS, in the first procedure, precluding to advance the LV lead. Because of the absence of target CS branches proximally to the stenosis and the previous documented positive response to lateral LV wall pacing, an angioplasty of the CS was performed and subsequently the LV pacing lead (Easytrak 2 4517, Guidant, St Paul, MN, USA) was inserted to reach the lateral branch of the CS. Unfortunately, a local device infection occurred 2 months later and a complete device removal was decided. After the system removal, a new CRT system was implanted contralaterally (i.e. on the right side). The venography revealed a restenosis in the middle CS, precluding the implantation of a new CS lead in the previous target position. Thus, a new balloon angioplasty was performed and the lead (Quicksite 1056K, St Jude Medical, Andover, CA, USA) was advanced in the same lateral CS branch. Procedural time was higher in the infection group than in the malfunction group, whatever the fluoroscopy time was similar. We did not find any relationship between the leads dwell time and the need to use more complex extraction/reimplantation techniques (*Table 2*).

One-year follow-up

One year after LV lead reimplantation, we observed five deaths (overall mortality: 5.5%; three non-cardiac deaths), which only occurred in the infection group (7.5% mortality for this subgroup); no deaths were observed in the malfunction group and in patients who did not undergo reimplantation. The incidence of infection (no cases of sepsis or endocarditis) was 4.4% in the overall reimplanted population; no relapses were observed in patients with previous diagnosis of local infection. No infection recurrence occurred in patients who did not undergo reimplantation. Statistical analysis showed a trend in higher incidence of infection after ipsilateral reimplantation ($P = 0.054$). The incidence of system malfunction requiring re-intervention was globally 6.7% and was similar in both groups (*Tables 3 and 4*).

Discussion

We report the largest single-centre experience of CRT device reimplantation after CS lead extraction. The major findings of this study are the following:

- The CS lead extraction and consequent reimplantation is an effective and safe procedure, when performed by experienced operators, and generally the reimplantation can be successfully

Table 3 Complications rate after 1-year follow-up (including perioperative complications)

	Malfunction group ($n = 23$)	Infection group ($n = 67$)	Overall ($n = 90$)
Patients with 1-year follow-up	23/23 (100%)	65/67 (97%)	88/90 (97.8%)
Lost at follow-up	None	2/67 (3%)	2/90 (2.2%)
Deaths	None	5/67 (7.5%)	5/90 (5.5%)
•Heart failure		2/67 (3%)	2/90 (2.2%)
•Sudden deaths		None	None
•Non-cardiac deaths		3/67(4.5%)	3/90 (3.3%)[a]
Infection	2/23 (8.7%)	2/67 (3%)	4/90 (4.4%)
•Local	2/23 (8.7%)	2/67 (3%)	4/90 (4.4%)
•Systemic	None	None	None
System malfunction requiring re-intervention	2/23 (8.7%)	4/67 (6%)	6/90 (6.7%)
•During the same hospitalization	None	2/67 (3%)	2/90 (2.2%)
Total complications (death/infection/malfunction with re-intervention)	4/23 (17.4%)	11/67 (16.4%)	15/90 (16.7%)

[a]One death caused by an abdominal aortic aneurism rupture, one death caused by a stroke after cardiac surgical intervention (in-hospital death), and one death caused by an acute respiratory distress.

Table 4 Characteristic of patients with infection at follow-up

Case	Device	Group	Time between extraction and reimplantation (days)	Reimplantation side	Ipsilateral	Fluoroscopy time (min)	Infection timing (weeks)	Outcome
1	CRT-ICD	Malfunction	0	Left	Yes	80[a]	11	Removal and reimplantation on the right side
2	CRT-ICD	Malfunction	0	Left	Yes	23[b]	8	Removal and reimplantation on the right side
3	CRT-ICD	Infection (systemic)	24	Left	Yes	18[c]	12	Removal and reimplantation on the right side
4	CRT-ICD	Infection (systemic)	2	Right	Not	50	22	Removal and reimplantation on the left side

CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.
[a]The procedure have required a balloon angioplasty.
[b]Reimplantation failure.
[c]We changed the pocket from a prepectoral to a subepectoral site; the procedure was complicated by a large haematoma.

performed using conventional techniques, regardless of the implantation side.

- The 1-year mortality in our cohort was particularly low, whereas the overall incidence of infection at follow-up was higher than first implant conventional procedures.[11,12] The incidence of malfunction at follow-up was comparable with CRT first implant's data in high-volume centre.[13]

Coronary sinus lead reimplantation procedural outcome

In our point of view, the key points of such a procedure are the right-sided approach after CRT device removal in nearly all cases with previous diagnosis of infection and the likelihood that no CS branches were available at the moment of LV pacing lead reimplantation. Despite the high rate of right-sided reimplantation (64.4% in overall population), we successfully performed the procedure in all but four patients. Whatever the first position was, the CS lead was placed in the LV postero-lateral region in >60% of patients, thus confirming the feasibility of a proper CRT after lead extraction in the majority of the patients. Moreover, successful reimplantation was obtained using standard facilities, whereas additional tools (i.e. balloons for angioplasty) were reserved only for selected cases, in which a new implant was complicated by the presence of CS adherences and thrombotic occlusions after lead extraction. In these cases, angioplasty within the CS or/and

its tributaries was necessary in order to perform a new CRT implant. Although some authors demonstrated the feasibility of CS angioplasty to allow transvenous LV lead implant, few data on the effect of balloon angioplasty in the post-extraction procedures are currently available.[14,15] The fibrous adherences could prevent from achieving a satisfactory result after angioplasty; this points out the difference between an angioplasty performed in a natural narrowing of the vessel rather than an angioplasty on a post-extraction stenosis. Whatever the success of the CS angioplasty, we cannot exclude that the long duration of the procedure might favour a device infection in the follow-up, as happened to one of our patients.

One-year follow-up

In our study, the 1-year mortality resulted lower compared with previously published studies. In a recent paper from the Cleveland Clinic group including patients who underwent lead removal and reimplantation only for infection,[16] the in-hospital mortality was 4.6% and 1-year mortality was 17%, whereas in our experience the mortality was, respectively, 1.1 and 5.5%. Our data still remain remarkable, either if we consider only the infection group [in-hospital mortality: 1/67 (1.5%); 1-year mortality: 5/67 (7.5%) including three non-cardiac deaths] or if we include the patients with a previous infection, who did not undergo reimplantation [in-hospital mortality: 1/88 (1.1%); 1-year mortality: 5/88 (5.7%)]. Previous studies showed that mid-long-term mortality was high in patients undergoing lead extraction for infectious indication; particularly, systemic infection, bacteremia, C-reactive protein, and echocardiographic evidence of vegetations were considered predictors of mortality.[17,18] The lower number of patients with systemic infection in our population compared with Cleveland Clinic Group (20 vs. 41.5%)[16] could explain the different outcome.

We do not know if an increasing risk should be associated to the condition of CRT recipient, although a recent study found that outcomes and the risk of death were not influenced by infection, surgical revision, and lead/device replacement.[19]

The overall incidence at follow-up of infection was higher than first implant conventional procedures,[11,12] but comparable with reimplantation data in other high-volume centers.[20] We did not observe relapses in the group with previous local infection, but only in patients with previous diagnosis of systemic infection (two cases); new cases of infection (two cases) were also observed in the malfunction group. In three out of four patients with infection at follow-up, the reimplantation has been performed ipsilaterally, in two cases for malfunction and in one case for systemic infection (*Table 4*). We have observed a trend in higher infection rate in ipsilateral reimplantation, whatever this study was not performed to evaluate whether the delayed ipsilateral reimplantation could be a safe reimplantation strategy. However, following current guidelines recommendations, we have nowadays abandoned this kind of policy in patients with previous diagnosis of infection.[21] The relatively high incidence of infection in our population could be correlated with the low mortality rate. In other comparable experiences with lower incidence of infection at follow-up,[16] ~3% of the patients died after extraction for sepsis or multiorgan system failure during the same hospitalization. These patients would have been at high risk of relapse in case of survival anyway. The presence of refractory heart failure, the long duration of CRT reimplantation, and the previous diagnosis of infection represent, in our opinion, the most probable causes of the high rate of infection at follow-up, but the relatively small sample size of our population does not allow to confirm these remarks under a statistical point of view. Finally, the incidence of malfunction was comparable with first implant data from high-volume centres,[13] emphasizing the feasibility and effectiveness of this particular procedure.

Limitations

This study is a retrospective analysis that is subject to the biases of non-experimental designs. The population study was small and limited to a single, high-volume centre and the results could be different at other institutions. We did not have data on how many patients had the LV lead reimplanted in the same LV cardiac segment/CS vein; for these reasons, we do not know whether implanting the lead in a different LV segment could have influenced the reimplantation results. Thus, strong and definitive conclusions regarding the outcome of this unusual population cannot be drawn.

Conclusion

In conclusion, LV lead reimplantation is an effective and safe procedure, even using a right-sided approach. These results may be reached with standard techniques and facilities, reserving additional tools (i.e. balloons for angioplasty) for selected cases, in which the new implant was complicated by the presence of CS adherences and veins occlusion after lead extraction. Coronary sinus angioplasty should be used cautiously, waiting for more extensive data demonstrating its effectiveness and safety also in the follow-up. The one-year follow-up showed a low mortality rate (5.5%). No relapse was observed in patients with previous diagnosis of local infection and contralaterally reimplanted, whereas the infection was considerable in patients referred for malfunction or sepsis.

Conflicts of interest: none declared.

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