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ORIGINAL RESEARCH

The Loop Technique in Cardiac Resynchronization Therapy: A Prospective Cohort Study

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Objective: A new approach called the loop technique has been proven safe and effective for repeated intraoperative transvenous left ventricular (LV) lead dislocations during cardiac resynchronization therapy (CRT) in a 3-year follow-up. This study aimed to report on the 5-year safety and effectiveness of the loop technique.

Methods: This study was a prospective cohort study. Forty-four patients who underwent CRT device implantation at the Cardiology Department of Shaanxi Provincial People's Hospital between January 2013 and June 2019 were included. Data on patient demographics, medical history, laboratory test results, and echocardiography images at admission were collected. The loop technique was performed with repeated intraoperative dislocations of the LV lead. The intraoperative CRT parameters were also recorded. All patients were followed for 5 years. Several auxiliary examinations were performed during follow-up.

Results: The 44 patients were divided into the traditional operation group (n=36, 81.8%) and loop technique group (n=8, 18.2%). The baseline patient characteristics were almost balanced. During the 5-year follow-up, 8 (22.2%) patients in the traditional operation group and 2 (25.0%) patients in the loop technique group died. No lead dislocation or other complications related to CRT were observed. There were no significant differences in mortality rate (P=0.87), cardiac function (P=0.56), echocardiographic indices, threshold (P=0.58), or impedance (P=0.22) of the LV lead. There were no significant differences in the threshold and impedance between postoperative, 3-year, and 5-year follow-ups in the loop technique group (P=0.53).

Conclusion: The loop technique is an ideal solution for repeated intraoperative LV lead dislocation during CRT implantation.

Keywords: loop technique, new technique, cardiac resynchronization therapy, left ventricular lead, repeated intraoperative dislocations

Introduction

Cardiac resynchronization therapy (CRT) is recommended for patients with heart failure (HF) with clinical symptoms, a left ventricular ejection fraction (LVEF)≤35%, and an RQS duration≥130ms according to guidelines.[1] CRT has been proven to improve symptoms, enhance cardiac function, and reduce morbidity and mortality by reversing remodeling and diminishing functional mitral regurgitation.[2–4] However, almost one-third of CRT recipients fail to respond to treatment, limiting their underutilization and effectiveness.[5,6] Many factors have been related to response to CRT, including the left ventricular (LV) lead position.[7,8] The location of the LV lead is a strong predictor of CRT outcomes.[9,10] The ideal location is a branch of the coronary sinus.[11] Despite many technological improvements, such as operative approaches and auxiliary tools, LV dislodgement rates are 5–10%.[11–14]

Based on the clinical practice, a novel technique named the loop technique was developed by our team. Briefly, the loop technique was applied when LV lead dislocations recurred, despite the lead configurations of different manufacturers. The LV lead was looped in a vessel that was close to the target vessel.[15] We first reported the use of the new technique in 5 patients. At the one year follow-up, the pacing and sensing parameters were satisfactory, LV structure and function improved, and no LV lead dislocations were observed.[15] Subsequently, a 3-year follow-up HF with a CRT implant cohort was studied. There was no significant difference in the therapeutic effect between the traditional operation and loop techniques, and no complications were

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associated with this technique.[16] The above data revealed that this technique could be a safe and effective alternative method when repeated intraoperative LV lead dislocations occur during CRT implantation. Nevertheless, the long-term safety and effectiveness of the loop technique remain unclear.

In the current study, we sequentially used HF in a CRT cohort, which was studied in the 3-year prognosis, and reported the 5-year safety and effectiveness of the loop technique.

Methods

Study Population

This study was a prospective cohort study. The study population consisted of 44 patients who underwent CRT device implantation at the Cardiology Department of Shaanxi Provincial People's Hospital between January 2013 and June 2019. The inclusion and exclusion criteria were published.[16] A flowchart of this process is shown in Figure 1. This study complied with the Declaration of Helsinki (as revised in 2013) and was approved by the Ethics Committee of Shaanxi Provincial People's Hospital, Xi'an, Shaanxi, China (No. SPPH-LLBG-12-3.2). Written informed consent was obtained from all the participants.

Date Collection

Data on patient demographics, medical history, laboratory test results, and echocardiography images at admission were collected using a hospital information system.

Loop Technique in CRT

Current strategies for the optimal CRT implementation and the detailed steps of the loop technique in CRT have been published previously.[15,17] The loop technique was an alternative method during the same procedure when repeated LV lead dislocation (≥2 dislocations) occurred and at least two different manufacturers' lead configurations were tried.

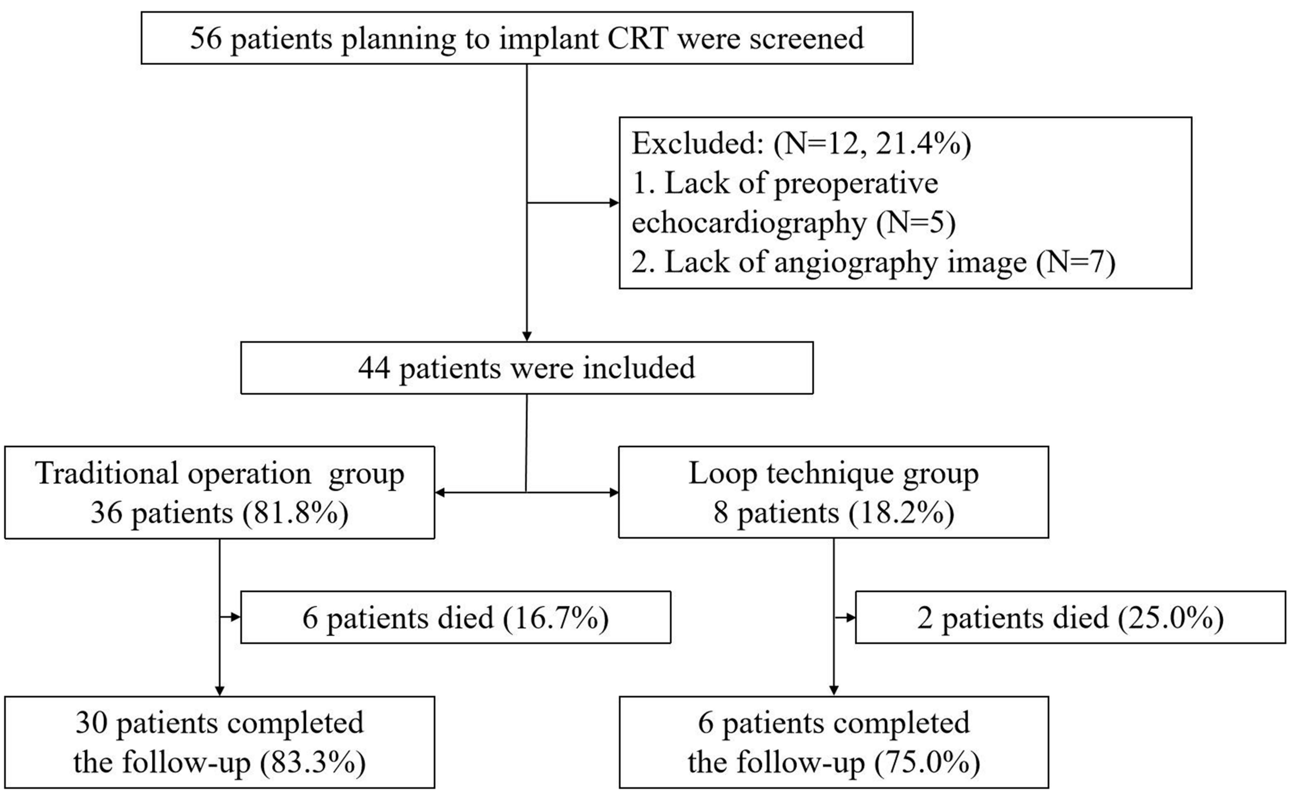

Figure 1 Cohort selection flow diagram.

Instead of moving straight to the target vessel, the LV lead runs into a vessel adjacent to the target vessel and then turns into the target vessel. Finally, the LV lead forms a loop in the vessel adjacent to the target vessel (Figure 2 and Supplementary Figure 1). The intraoperative CRT parameters were also recorded.

Follow-Up

The endpoint (all-cause mortality) and follow-up methods were published previously.[16] Follow-up ended on the date of endpoint occurrence or at five years postoperatively. Several auxiliary examinations, including chest X-ray imaging, echocardiography, and pacemaker programming, were recorded separately at the 3-year and 5-year follow-up.

Statistical Analysis

Continuous variables are presented as the mean±standard deviation (SD). The Kolmogorov—Smirnov test was used to assess the normality of the continuous variable distributions. Student's *t*-test and one-way ANOVA were used to compare continuous variables, as appropriate. Categorical variables are presented as frequencies (percentages). The $\chi 2$ test was used to analyze the differences between categorical variables. All computations were performed using SPSS software v22.0 (SPSS Inc., Chicago, Ill., USA). A two-tailed test was used to determine statistically significant differences ($P < 0.05$).

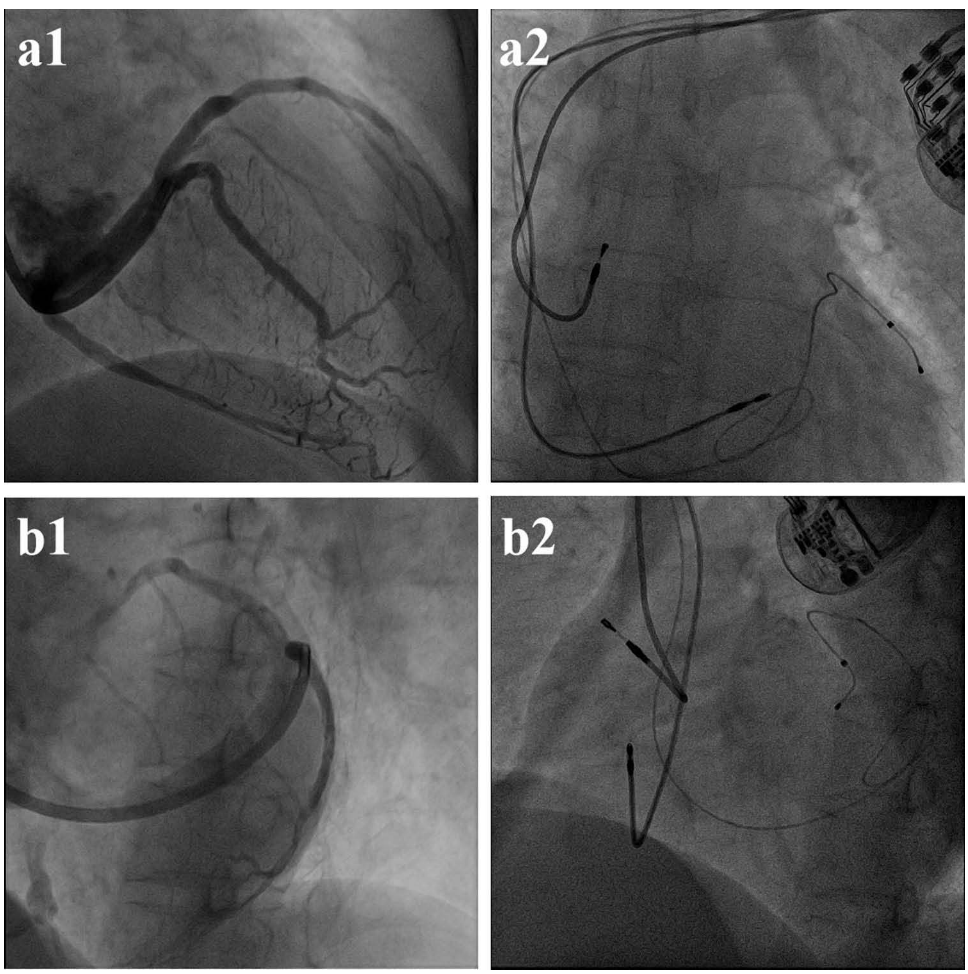

Figure 2 Coronary sinus angiography from (a1) right anterior oblique (RAO) 30° and (b1) left anterior oblique (Lao) 60° projections. Final position of the left ventricular lead by the loop technique from (a2) RAO 30° and (b2) LAO 60° projections.

Results

Baseline Characteristics of the Study Population

The 44 patients were divided into the traditional operation group (n=36, 81.8%) and loop technique group (n=8, 18.2%). Operative characteristics were published in a previous study.[16] On the whole, no significant differences between the two groups were observed with respect to most peroperative indices, including gender, age, underlying heart disease, cardiac function and echocardiography indexes, except for the N-terminal pro-brain natriuretic peptide (NT-proBNP), which was lower in the loop technique group than in the traditional operation group (575.0pg/mL vs 2453.0pg/mL, P=0.03).

In addition, there were no significant differences in intraoperative pacing and sensing parameters between the two groups (the threshold: 0.95 vs 1.43, P=0.14 and impedance: 771.50 vs 826.50, P=0.84).

Follow-Up and 5-Year Prognosis

The mean follow-up was 56.4 months (interquartile range: 48.0–64.5 months). During the 5-year follow-up, 8 (22.2%) patients in the traditional operation group and 2 (25.0%) patients in the loop technique group died. There was no significant difference in the mortality rate (P=0.87). In both the traditional operation and loop technique groups, no complications related to CRT were observed, including lead dislocation. Chest X-ray imaging verified that the location of the CRT remained unchanged from postoperative to 5-year follow-up in the loop technique group (Figure 3). The characteristics of the two groups at follow-up are shown in Table 1. There were no significant differences in cardiac function or echocardiographic indices between groups. In the traditional operation group, the threshold and impedance of the LV lead were 1.42±0.75 and 903.57±216.94, respectively. In the loop technique group, the threshold and impedance were 1.17±0.29 and 739.00±79.57, respectively. There were no significant differences in these parameters between the two groups (P=0.58 and P=0.22). In addition, there were no significant differences in the threshold and impedance between postoperative, 3-year, and 5-year follow-ups in the loop technique group (P=0.53).

Discussion

In this report, we showed that the loop technique can be used successfully to fix the LV lead when repeated dislocations occur intraoperatively. Additionally, we performed relevant examinations using this new technique, without complications, five years after implantation.

Appropriate location of the LV lead is essential for the CRT working correctly.[7,8] Previous studies have attempted to use different types of leads to solve LV lead dislocations. Vado et al studied 45 patients with HF with successful implantation of a quadripolar LV lead; however, 6.6% suffered from acute dislodgement.[18] Forleo et al conducted a registry study with a larger

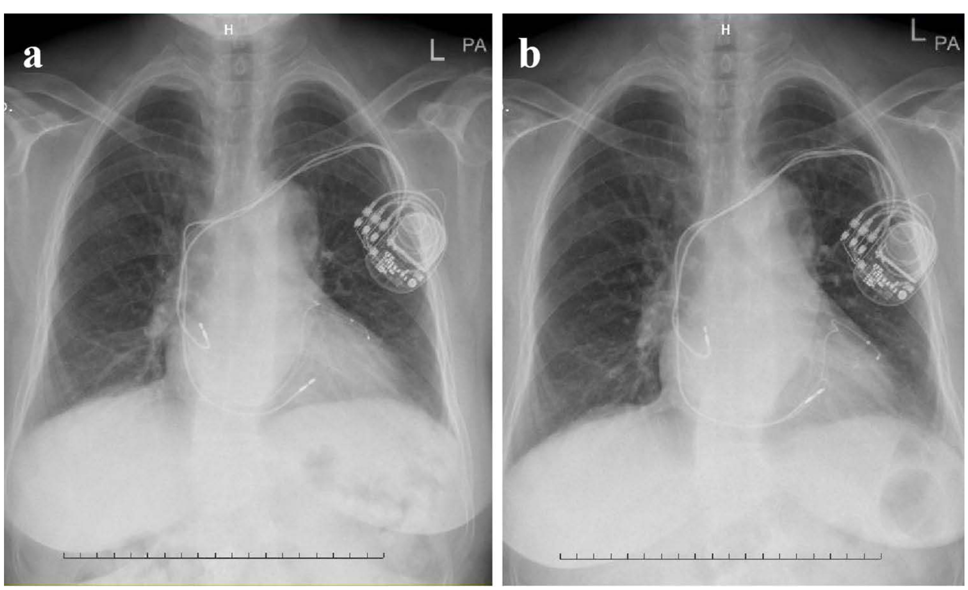

Figure 3 Chest X-ray image of the position of the left ventricular lead by the loop technique at (**a**) postoperation and (**b**) the 5-year follow-up.

Table 1 Postoperative Characteristics of Patients with Heart Failure According to Operations of CRT Implantation

Variable	Traditional Operation Group n=28	Loop Technique Group n=6	P value
NYHA			
II	14 (50.0)	2 (33.3)	0.56
III	10 (35.7)	4 (66.7)	
IV	4 (14.3)	0 (0.0)	
Echocardiography indexes			
LVEF (%)	35.9±10.4	46.0±15.4	0.18
LVESD (mm)	58.6±13.3	47.3±25.6	0.27
LVEDD (mm)	70.7±12.8	53.3±28.1	0.10

sample size. Although the success rate and effect were acceptable, other problems could not be ignored, including the overuse of a quadripolar LV lead and lead dislodgment.[19] Luedorff et al used the Attain Starfix active fixation lead in 82 patients with CRT devices implanted during the intraoperative dislodgement of passive fixation leads. The success rate was 90% and the therapeutic effect was stable However, one patient received a revision procedure due of instability.[12] As shown above, these newly designed leads significantly decrease the dislocation rate and other complications such as phrenic nerve stimulation. However, the use of these leads is limited for two primary reasons. The first is the technical barrier. Many medical centers have no prior experience at the beginning of learning. The second issue concerns long-term safety and effectiveness. The longest follow-up period was 18 months in the studies above; therefore, the possibility of problems arising relating to these new leads over a longer period cannot be excluded. The loop technique uses a traditional biventricular system and no other devices are required. It is relatively easy for experienced interventional cardiologists to create a loop in a vessel. The follow-up period was 5 years in the present study was five years, which was significantly longer and more convincing.

Variable vein anatomy is another reason why lead placement is a technically challenging procedure; therefore, clinicians try other approaches. Kassai et al first proposed the transapical endocardial implantation of the LV lead.[20] They first performed this new technique in 10 patients with HF, and detected only one lead dislocation was detected.[21] Subsequently, the sample size was increased to 20 patients. Eighteen patients underwent minithoracotomy and transapical puncture and two patients underwent lead dislocation.[22] Another study found the same results; although transapical endocardial LV lead implantation was a choice, intraoperative and early postoperative dislocations were observed.[23] Additionally, this new technique is not applicable to every patient because of its indications and incidental anticoagulation therapy. In addition, transapical endocardial LV lead implantation could have adverse consequences, including bleeding and pneumothorax, because of transthoracic LV puncture. These complications can be avoided by the percutaneous implantation of a transapical endocardial LV lead, which requires further development. Geller et al regarded transseptal endocardial LV lead implantation as an effective approach for CRT. They reported significant improvement in cardiac function in 54 patients. Nevertheless, relatively high rates of early lead dislocation (5%) and thromboembolism (7%) have caused concern.[24] The loop technique shares the same indications as traditional CRT implantation, and no additional treatments were added to the patients. Most importantly, no dislocations or other complications such as thromboembolism were observed during the 5-year follow-up period.

Taking full advantage of the existing instruments has been attempted to solve LV lead dislocations. Previous research reported that retaining the guidewire could prevent dislocations in 6 patients during a 6-month follow-up.[25] Mischke et al reported that magnetic guidewire navigation-assisted LV lead placement could increase the success rate of guidewire access to the target vessel.[26] However, guidewire-related complications should be considered. A ruptured magnetic guidewire has been reported in the study.[26] Sharifkazemi et al placed a stent in 35 patients, and the results showed no significant differences in pacing threshold and impedance during follow-up compared with implantation measurements.[27] Szilagyi et al performed stent implantation in 36 patients because of intraoperative and postoperative dislocation. One-year follow-up revealed that this technique is useful and safe.[28] Geller et al implanted a stent in the SB of the coronary sinus in 312 patients. However, LV pacing threshold increases, and phrenic nerve stimulation has also been observed in several patients.[29] Demir et al also verified that stenting in the coronary sinus side branch is an effective method to stabilize dislocated leads.[30] Compared with the above techniques, the loop technique does not utilize additional instruments, which not only reduces costs, but also avoids complications related to these operative instruments.

More significantly, left bundle branch area pacing (LBBAP) was first proposed in 2017, and its better pacing physiology verified that this modality could be an ideal resolution to achieve CRT in patients with HF and left bundle branch block (LBBB).[31,32] Previous studies have demonstrated that LBBAP narrows the QRS complex and improves LVEF with a shorter duration of X-ray exposure during the operation, and the operation is not easily affected by vascular anatomy when the lead is implanted through the ventricular septum.[33,34] In addition to complications associated with conventional pacing patterns, other complications related to LBBAP have also been a subject of interest, including right bundle branch block (RBBB) and an increase in capture thresholds. In addition, some problems still limit the use of this technique, such as the complicated procedure and need for electrophysiological multichannel recording.[35]

The current study has several limitations. First, this study included only 8 patients in the loop-technique group. Large-scale studies are required to address this problem. Second, although our study was conducted up to 5 years after implantation, we cannot exclude longer-term issues regarding the loop technique. Third, it remains unknown whether the loop technique reduces the proportion of non-responders to CRT.

Conclusion

In conclusion, the loop technique, which means that the LV lead runs into a vessel adjacent to the target vessel firstly, and then makes a turn into the target vessel, and finally forms a loop in the vessel adjacent to the target vessel, is an ideal solution for repeated intraoperative LV lead dislocations during CRT implantation.

Abbreviations

CRT, cardiac resynchronization therapy; HF, heart failure; LBBAP, left bundle branch area pacing; LBBB, left bundle branch block; LV, left ventricular; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; RBBB, right bundle branch block.

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Disclosure

All authors report no conflicts of interest in this work.

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