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A Novel Approach for Endocardial Resynchronization Therapy: Initial Experience with Transapical Implantation of the Left Ventricular Lead

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ABSTRACT

Background: Coronary sinus lead placement for transvenous left ventricular (LV) pacing in cardiac resynchronization therapy (CRT) has a significant failure rate at implant and a considerable dislocation rate during follow-up. For these patients epicardial pacing lead implantation is the most frequently used alternative. Recent data support endocardial lead implantation through the atrial septum and the mitral valve, because this method provides further hemodynamic advantages. On the other hand transseptal CRT carries a significant risk for device related infective endocarditis of the mitral valve. The aim of this prospective, nonrandomized study was to demonstrate the feasibility of a fundamentally new approach for endocardial LV lead implantation.

Methods: We performed 12 transapical LV lead implantations in 10 end-stage heart failure patients. In each operation an active fixation lead was placed into the LV cavity using standard Seldinger technique through the LV apex. By use of a J-shaped guide wire, the tip of the lead was positioned and fixed into the basal-lateral segment of the LV under fluoroscopy guidance. Pacing parameters were assessed and found to be optimal in all patients. The lead was conducted through the chest wall near the apex into a subcutaneous tunnel up to the pocket of the previously implanted device. After surgery the patients are anticoagulated with target anticoagulation level identical to mechanical valve prostheses.

Results: In 8 patients there were no major or minor complications related to this new technique. During the follow-up period (mean 7.2 ± 4.1 months) all patients responded favorably to the treatment. One lead dislocation and 1 pocket infection were detected; the lead repositioning and replacing could be performed without reopening of the pleural cavity.

Conclusions: The potential advantages of this new technique are that it is minimally invasive, endocardial, and does not involve the mitral valve. LV lead repositioning can also be performed minimally invasively.

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INTRODUCTION

The standard technique for cardiac resynchronization therapy (CRT) is transvenous left ventricular (LV) lead implantation performed by using the tributaries of the coronary sinus (CS). Despite recent improvements of this technique, the CS route does not always provide optimal result for lead positioning in a significant number of patients. Initially, the transvenous LV lead implantation had a failure rate of 10% to 15% at implant and during short-term follow-up [Abraham 2002]. Although this high failure rate has been remarkably improved in recent years, unsuccessful lead positioning and/or lead dislocation still occur in about 5%-10% of the patients. Furthermore, technically acceptable pacing parameters do not automatically ensure optimal clinical response to the therapy [Ypenburg 2009].

Table 1. Patient Characteristics

No. of patients	10
Age, y ± SD	60 ± 8.8
Male/female	8/2
Left ventricular ejection fraction, % ± SD	26.0 ± 7.8
Left atrium, mm ± SD	61.0 ± 9.8
Left ventricular end systolic dimension, mm ± SD	62.7 ± 10.8
Left ventricular end diastolic dimension, mm ± SD	73.7 ± 10.5

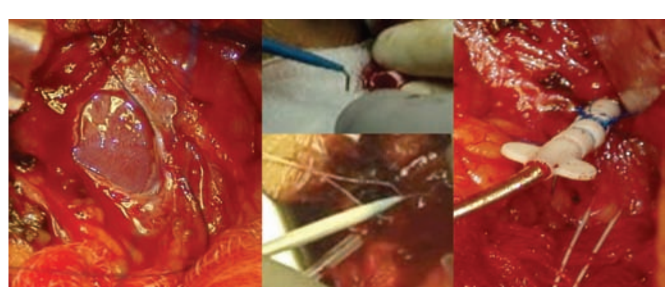

Figure 1. Steps of the transapical left-ventricular lead insertion.

Table 2. Classification of Failed Coronary Sinus (CS) Lead Placement

Causes of CS lead placement failure	No
Aberrant orifice of CS; no intubation	4
Phrenic nerve stimulation; high threshold	3
No suitable CS side branches	1
Recurrent dislocations of CS lead	2

For patients lacking an appropriate CS route, epicardial pacing is the most frequently used alternative. Although epicardial lead positioning is not difficult, some issues should be considered as possible limitations, such as LV dilatation, difficulties reaching the most delayed segment of the lateral wall, and pleural and pericardial adhesions. Moreover, the main limitation of the epicardial lead implantation is the invasiveness of this method compared to transvenous implantation.

A fundamentally new approach using transapical implantation of an active fixation endocardial pacing lead was recently reported [Kassai 2009]. This technique is based on direct puncture of the left ventricular apex using the standard Seldinger technique [Kassai 2009]. The aim of this study is to summarize our initial experience and short-term follow-up with this new method.

MATERIALS AND METHODS

Patient Population

We performed transapical LV-lead implantations in 10 end-stage heart failure patients (Tables 1 and 2). Inclusion criteria were chronic heart failure in New York Heart Association functional class III and IV measured under ambulatory conditions, with QRS duration ≥125 ms and LV ejection fraction ≤35%, failure of percutaneous CS lead implantation, and acceptance for surgical procedure by the multidisciplinary team. Patients were excluded if they had thrombus in the LV cavity, acute or subacute myocardial infarction involving the apex, chest-wall abnormalities near the apex, severe obstructive pulmonary disease, contraindications for anticoagulation or narcosis, or the presence of any temporary conditions leading to high risk, such as fever or blood coagulation disorders.

Informed consent was obtained from all patients before surgery, with special attention to the risk of systemic embolization (including stroke) and the side effects of anticoagulation.

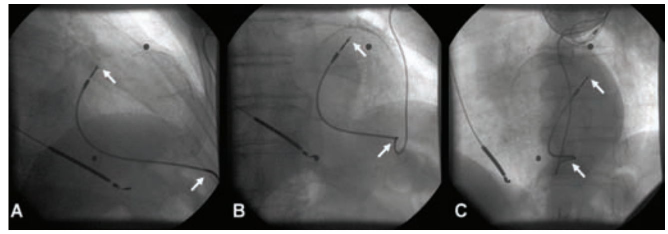

Figure 2. Final position of the left ventricular endocardial electrode from right anterior oblique (A), antero-posterior (B), and left anterior oblique (C) projection. The arrows show the tip in the endocardium and the location of the apical puncture.

Main Features of the Implantation Procedure

We previously reported the detailed operative technique of transapical LV-lead insertion [Kassai 2009]. We describe the most important issues for the novel method here.

The initial transthoracic echocardiography for locating the LV apex is more useful if the patient is positioned exactly

Table 3. Detailed Results of the Implantations*

Patient No.	Operation No.	Age, y	Sex	Transapical LV Lead†	Follow-up, months	Preoperative NYHA	Postoperative NYHA
1	1	72	M	Guidant/4096/52 cm/8 Fr	13	IV	II
2	2	57	F	Vitatron/ICQ09B/52 cm/7 Fr	10	IV	III
3	3	57	M	Vitatron/ICQ09B/52 cm/7 Fr	10	IV	II
4	4	69	F	Medtronic/4076/85 cm/7 Fr	9	IV	II
5	5	53	M	Guidant/4096/52 cm/8 Fr	9	IV	III
6	6	65	M	Vitatron/ICQ09B/52 cm/7 Fr	8	IV	
	12	(Due to lead dislocation)		Medtronic/4076/85 cm/7 Fr			II
7	8	53	M	Medtronic/4076/85 cm/7 Fr	8	IV	II
8	9	46	M	Medtronic/5076/52 cm/7 Fr	2	IV	
	10	(Due to pocket infection)		Medtronic/5076/52 cm/7 Fr			III
9	11	71	M	Medtronic/4076/85 cm/7 Fr	2	IV	II
10	12	57	M	Medtronic/5076/52 cm/7 Fr	1	IV	II

*NYHA indicates New York Heart Association; LV, left ventricular.
†Manufacturer/type of lead/length of lead/introducer size.

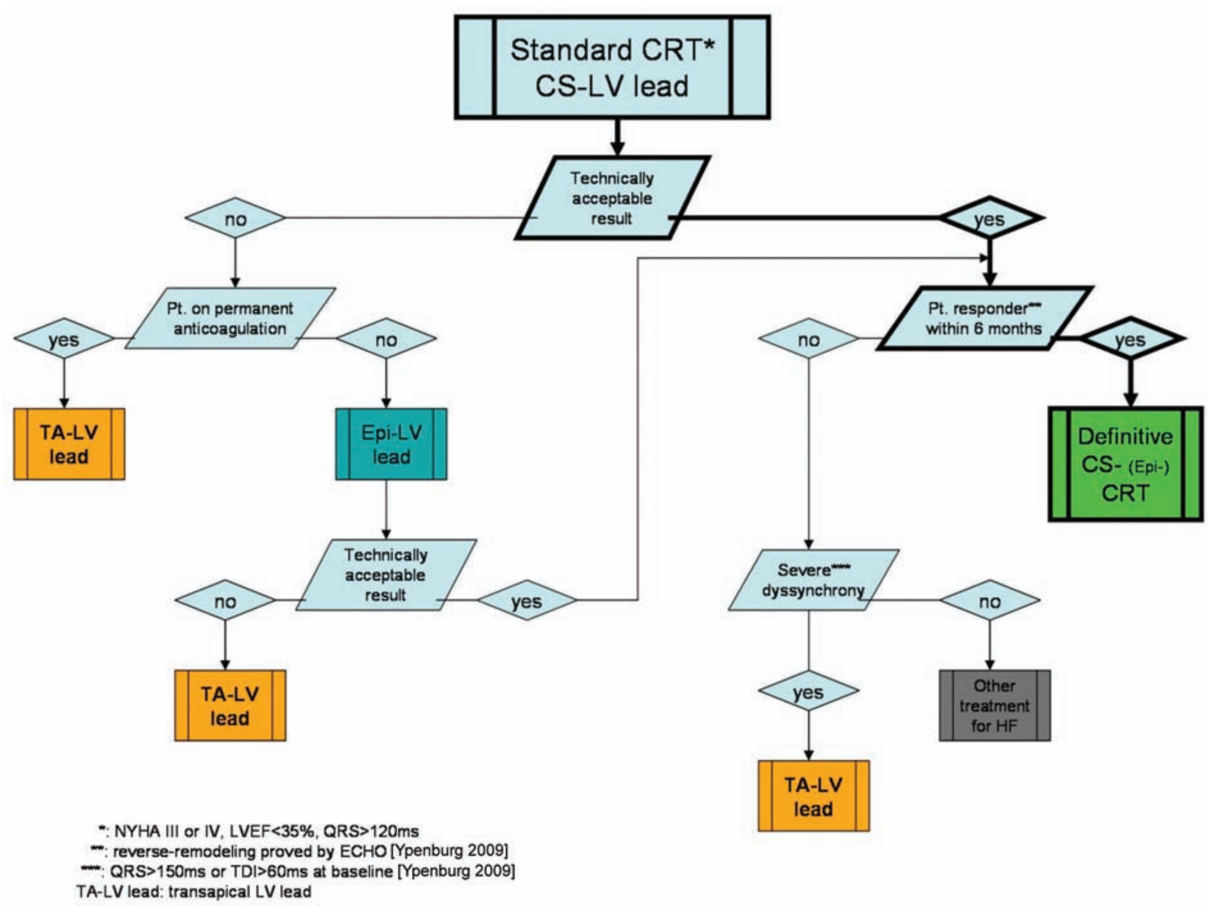

Figure 3. The proposed decision-making algorithm. CRT indicates cardiac resynchronization therapy; CS, coronary sinus; LV, left ventricular; TA, transapical; HF, heart failure [Ypengburg 2009].

the same during the surgical procedure. Various respiratory conditions also can cause different anatomical correlations between the apex and the chest wall. Proper location of the apex can facilitate the performance of the smallest successful incision in the most appropriate intercostal space. Easy and safe achievement of the apex is illustrated on the first panel of Figure 1.

In this approach, the tip of the needle is absolutely eye controlled during the apex puncture so that the minimal backflow of the blood is enough to allow the safe insertion of the guide wire into the LV cavity. Dilation of the apex hole with a peel-away sheath is the most proarrhythmic part of the insertion, as is well illustrated on the attached intraoperative video (see attached video file). Extra attention from every member of the team is necessary during this maneuver.

A large amount of blood may erupt through the sheet before insertion of the pacing electrode, therefore quick insertion or fingertip control is necessary. Unobserved and untreated hypovolemia can cause air suction through the sheet into the LV cavity in diastole. Controlling the volume conditions is absolutely necessary during this type of lead insertion.

The active fixation of the electrode tip can be difficult and unstable in the most delayed segment of the LV wall when endocardial scarring is present. Careful evaluation of the tip-to-endocardium contact can prevent lead dislocation.

Two purse-string sutures around the puncture point applied as tourniquets are very safe and comfortable with pledge material from the surrounding pericardium. Manipulating with 2 sutures provides a bloodless field permanently around the puncture point. Fixing the lead-body with these sutures, as shown in the last panel of Figure 1, is very useful.

Figure 2 shows the recommended electrode loop inside the LV cavity. It provides the most stable electrode-tip position with the shortest length of the electrode inside. This position and electrode curve should be checked during the reverse remodeling. Increasing distance between the apex and the chest wall caused by pleasing changes of the heart can pull out the electrode from the LV cavity. Early reoperation with forward pushing and apex-site refixation of the lead can prevent total dislocation.

RESULTS

In 8 patients there were no major or minor complications related to this new technique. During the follow-up period (mean 7.2 ± 4.1 months) all patients responded favorably to the treatment (Table 3). One lead dislocation and 1 pocket infection were detected; the lead repositioning and replacing could be performed without reopening of the pleural cavity. One patient's symptoms did not change after the procedure; however, the numbers of her hospitalizations decreased and her New York Heart Association functional class improved. Technically, all the implanted and 2 replaced leads worked properly in all patients. One episode of self-terminating ventricular tachycardia was detected by 1 of the implantable cardioverter defibrillator.

DISCUSSION

To achieve CRT, alternative methods are necessary for patients in whom CS lead implantation has failed. Epicardial LV lead implantation is the most frequently used alternative, although this approach requires heart surgery.

Recent data support endocardial lead implantation through the atrial septum and the mitral valve [Gelder 2007] because the endocardial pacing provides further hemodynamic benefit [Garrigue 2001]. An activation sequence originating from the endocardial surface has advantages over epicardial stimulation (note: CS leads and surgically implanted epicardial leads provide epicardial stimulation). Endocardial stimulation has shown to be associated with a greater aortic and mitral time velocity integral, an increased left ventricular fractional shortening, and an improvement in the regional electromechanic delay in comparison with epicardial stimulation. In regard to this beneficial effect, the number of responders for cardiac resynchronization therapy could be increased, but the possible side effects associated with transseptal implantation are not negligible. When a foreign body enters from the right atrium into the left side of the heart in close and permanent contact with the mitral valve, the risk of mitral endocarditis is increased [Kassai 2008]. Moreover, endocarditis occurs the outcome is presumably even more deleterious than the potentially lethal right-sided pacemaker endocarditis. The infected mitral valve very often needs surgery itself. This situation is somewhat of a paradox, because most of these indications are based on inoperability of the patient. Beyond this, under these special conditions mitral valve surgery carries a higher risk for mortality and morbidity.

The transapical method [Kassai 2009] can overcome most of the above-mentioned potential problems because it is minimally invasive, provides endocardial pacing, and avoids problems associated with contact with the mitral valve.

In the last 40 years cardiac operations have often involved the apex of the heart because it is useful for left-heart decompression, arterial cannulation for cardiopulmonary bypass, and positioning with a suction device for off-pump coronary artery bypass surgery, aortic valve bypass, transapical aortic valve implantation, and apical cannulation for ventricular assist devices. Our new method has been developed on basis of these experiences.

According to our initial experience, we recommend transapical LV lead insertion for patients in whom CS lead placement has failed and permanent anticoagulation is already present. Obviously, a step further would be transapical endocardial LV pacing for nonresponders. Certainly, progress with these techniques requires larger-scale prospective randomized studies. These studies can be conducted when longer-term follow-up will be available. Based on the above-mentioned issues and our rather positive experience with this novel method, our proposed decision-making algorithm involving transapical CRT is presented on Figure 3.

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