Surgical epicardial left ventricular lead versus coronary sinus lead placement in biventricular pacing ☆

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Abstract

Objective: Biventricular pacing has demonstrated improvement in cardiac function in treating congestive heart failure (CHF). Two different operative strategies (coronary sinus vs. epicardial stimulation) for left ventricular (LV) pacing were compared. **Methods:** Since April 1999, a total of 86 patients (pts, age: 63 ± 10 years) with depressed systolic LV function (mean ejection fraction $24 \pm 9\%$), left bundle-branch-block (mean QRS 182 ± 22 ms) and congestive heart failure NYHA III or higher were enrolled. For biventricular stimulation coronary sinus (CS) leads were placed in 79 pts. Nine of these devices were converted to surgical epicardial LV-leads, because of CS-lead failure. In 7 patients epicardial LV-leads were initially implanted surgically, accounting for a total of 16 pts with surgical placed epicardial steroid-eluting LV-leads. For these, a limited left-lateral thoracotomy (7 ± 4 cm) was used. Thirty-three (38%) pts had an indication for a defibrillator. The mean follow-up time was 16.4 ± 15.4 months (0.1-45 months), representing 107.1 patient-years. **Results:** In the biventricular pacing mode, QRS duration decreased to 143 ± 16 ms ($P < 0.001$). Threshold capture of the CS-leads increased significantly compared to surgically placed epicardial leads (18 month control: 2.2 ± 1.4 V/0.5 ms vs. 0.7 ± 0.3 V/0.5 ms), which had no increase in threshold ($P < 0.001$). At the 18 month follow-up 7 CS-leads had a threshold of >4 V/0.5 ms vs. epicardial leads which were under 1.1 V/0.5 ms, except for one (1.8 V/0.5 ms). After CS-lead implantation 25 LV-lead related complications occurred, (failed implantation, CS-dissection, loss of pacing capture, diaphragm stimulation or lead dislodgment), vs. one dislodgement after surgical epicardial lead placement ($P < 0.05$). Correct lead positioning (obtuse marginal branch area) was achieved in all surgical epicardial placements but only in 70% with CS-leads ($P < 0.03$). In the follow up period, 9 pts died (4 cardiac related). Heart transplantation was necessary in 4 pts due to deterioration of the cardiomyopathy. **Conclusions:** Surgical epicardial lead placement revealed excellent long-term results and a lower LV-related complication rate compared to CS-leads. Although, the approach via limited thoracotomy for biventricular pacing is associated with 'more surgery', it is a safe and reliable technique and should be considered as an equal alternative.
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1. Introduction

Recent trials have proven the clinical and functional benefits of cardiac resynchronization therapy (CRT) by biventricular pacing in patients (pts) with severe heart failure and intraventricular conduction delay, principally left bundle branch block (LBBB) [1–5]. In particular, improvements in exercise tolerance, quality of life, increased systolic heart function, reduced hospitalization and slowed progression of the disease were observed. In the MIRACLE-trial (453 patients) [1] the combined risk of death or worsening of heart failure was significantly lower in the CRT-group compared to the control-group (12 vs. 20%). Moreover, by pooling the data of five large, prospective randomized trials (COMPANION [2], CONTAK-CD, InSync implantable-cardioverter defibrillator (ICD) [6], MIRACLE [1] and MUSTIC [4]) the all-cause mortality is now seen to be significantly reduced (odds ratio 0.74, 95% confidence interval 0.56-0.97) for the 2559 cumulative patients assigned either to CRT (1426 pts) or non-CRT (1133 pts) with a follow up duration of 6 month [7].

To experience these benefits of CRT, accurate multisite pacing is mandatory but challenging to accomplish.

To optimize CRT therapy, an additional lead needs to be placed in the right atrium to increase the preload of the failing heart by optimization of the atrioventricular delay. The most difficult part of this procedure is the implantation of the left ventricular (LV) lead: For CRT response, the LV lead has to be placed where optimal concordance is achieved between the left ventricular pacing site and the site of most delayed left ventricular mechanical activation [8]. Since introduction of biventricular pacing, several approaches and technical improvements have been described. Standard placement of the LV lead is either transvenous via the coronary sinus (CS) or surgical epicardial placed on the free LV wall [3,4,9–11].

While each technique bears its advantages and drawbacks, the method of choice is debated and has not yet been defined. We have used both approaches, transvenous and surgically placed epicardial. This paper reports our experience of biventricular pacing using both modalities.

2. Methods

2.1. Patient population

From April 1999 to January 2003, biventricular pacemakers were implanted in 86 patients. Although inclusion/exclusion criteria differed slightly over the time-period, in general patient selection was based on standard biventricular pacing indications: severe congestive heart failure rated as NYHA class III or IV despite optimized pharmacologic heart failure treatment; dilated ischemic or non-ischemic cardiomyopathy with left ventricular systolic dysfunction defined as LVEF <35% and left ventricular end-diastolic diameter >60 mm; and LBBB as reflected on the surface electrocardiogram by a QRS duration of >120 ms in spontaneous rhythm. Exceptions were made in 9 patients: two presented an EF of approximately 40% and 7 patients had clinically improved at time of operation to NYHA class II-III. All patients gave informed consent to the procedures. The patients' basic characteristics are listed in Table 1.

2.2. Mapping for lead placement

During the study-period we gave increasing attention to mapping procedures due to improved knowledge of the underlying pathophysiology of CRT. All patients underwent angiography prior to the procedure. Finally, the optimal left ventricular pacing site was determined by performing

preoperative and intraoperative electrophysiological and hemodynamic measurements and consideration of patients' anatomic condition. Currently, echocardiography with tissue Doppler imaging is most frequently performed in combination with electrophysiological measurements to determine the most delayed site of left ventricular wall contraction. Anatomically, the leads were placed most frequently just posterior to the obtuse marginal branch of the circumflex artery.

3. Implantation procedure

3.1. Transvenous approach via coronary sinus and its tributaries

The percutaneous procedures were performed using local anesthesia and antibiotic prophylaxis, except in 6 patients who received full anesthesia throughout the operation. All patients had standard monitoring (EKG, pulse oximetry and invasive arterial monitoring). The procedures were carried out fluoroscopy-guided. Right atrial and right ventricular pacing were established using standard transvenous lead models and insertion techniques through the cephalic vein (whenever possible) or subclavian vein.

Transvenous LV-lead placement via the subclavian route followed three steps:

1. Insertion of a pre-shaped guiding catheter into the ostium of the coronary sinus to provide a path for lead placement.
2. Obtaining a venogram during balloon occlusion to determine the patient's cardiac anatomy especially visualizing the venous system. The decision about the target-tributary of the CS venous system was determined at this time.
3. Placement of the lead through the dedicated guiding catheter into the coronary venous system. In principle, two different transvenous CS pacing lead systems were implanted during the study-period. One method was to deploy the lead with an over-the-wire technique (Guidant, Easytrak model 4510–4513; Medtronic Attain OTW model 4193) used in 44 patients. The leads were steroid-eluting, unipolar electrodes inserted by advancing them over a guide wire. Once in adequate position, anchoring was achieved by passive fixation of the lead. The second left ventricular pacing electrode was a shaped, passive fixation lead for stylet delivery implanted in 35 patients [Medtronic model 4189 (steroid-eluting, unipolar), Attain LV model 2187 (non steroid-eluting, unipolar), Attain CS 2188 (non steroid-eluting, bipolar)].

The lead was positioned as far as possible in the venous system, preferentially into a lateral or postero-lateral venous tributary to obtain the longest interventricular conduction time and a paced QRS duration that was as short as possible when pacing the two sites simultaneously (Fig. 1). If lateral veins were not accessible, or if pacing thresholds were unacceptably high (>3 V/0.5 ms), another branch was chosen. All device pockets were located in the left or right infraclavicular area.

Table 1
Baseline clinical characteristics of the study groups

	CS-group	Epi-group	P-value
Age (years)	64.0±9.9	62.9±9.7	0.28
DCMP (%)	73	75	0.56
ICMP (%)	27	25	0.89
Pacemaker (%)	59	75	0.55
ICD (n)	29	4	0.46
EF (%)	22±7	21±6	0.40

CS, coronary sinus; Epi, epicardial; DCMP, dilative cardiomyopathy; ICMP, ischemic cardiomyopathy; ICD, implantable cardioverter-defibrillator; EF, ejection fraction.
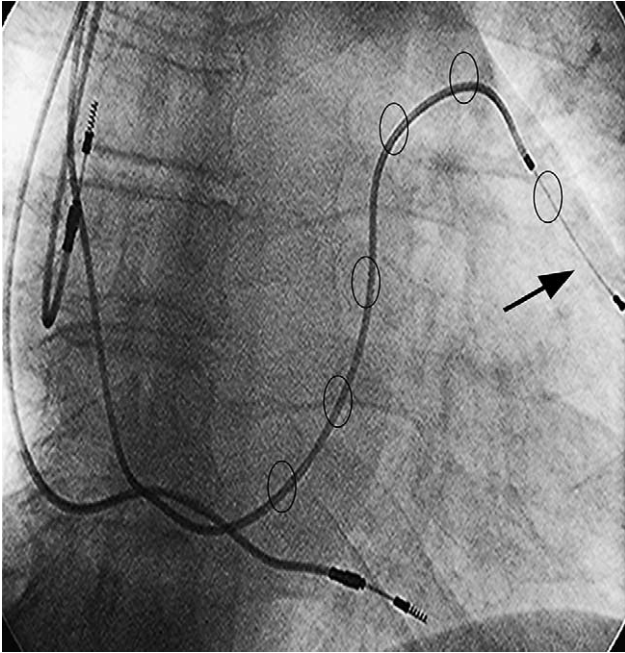
Fig. 1. Postoperative X-ray of a LV-lead (black arrow, Easytrak, Guidant) placed through the coronary sinus (circles) and conventional right atrial and right ventricular screw-in leads.

3.2. Mini-thoracotomy

The surgical epicardial implantation technique (Fig. 2) to the left lateral wall of the heart has been described elsewhere [11]. In brief: The procedures were performed in the operating room under general anesthesia and beating heart. All patients had standard monitoring (ECG, pulse

Fig. 2. Postoperative X-ray of a surgically placed bipolar epicardial LV-lead (white arrow, Capsure-Epi Model 4968, Medtronic Inc., Minneapolis, MN, USA). The patient received an ICD, an endocardially placed right ventricular shocking lead and a right atrial screw-in lead.

oximetry, invasive arterial monitoring and external defibrillator pads) and a Swan-Ganz catheter if needed. Transesophageal echocardiography (TEE) was carried out throughout the procedures. For right atrial and right ventricular pacing transvenous leads were placed in standard percutaneous, fluoroscopy-guided manner, except for three patients with thoracoscopic placement of the right ventricular lead. All device pockets were located in the left or right subclavicular space. After standard single lumen intubation the patient was placed in supine position with left chest elevated 30-40°. Following a 7 ± 4 cm left lateral, mid-axillary mini-thoracotomy at the sight of the fourth intercostal space the left lung was pushed back with a wet towel. The pericardium was opened anterior to the phrenic nerve while ensuring sufficient distance. The pericardium was fixed with traction-sutures to the skin rotating the heart to the right and creating optimal exposure to the lateral surface.

After mapping the left ventricle to determine the optimal pacing location, a unipolar or bipolar epicardial steroid lead (Capsure-Epi Models 4965 and 4968, Medtronic Inc., Minneapolis, MN, USA) was attached to the target area. Completing the threshold measurements and TEE assessment, the lead was secured with two sutures (Polypropylene 5/0 or 6/0). The connector of the lead was brought through the third intercostal space and tunneled submuscular to the device pocket and the pacemaker. The pericardium was partially closed. A small pleural drain (19 French Blake drain, Ethicon, Norderstedt, Germany) was inserted followed by standard wound closure. In 8 cases bipolar epicardial steroid leads (Capsure-Epi Model 4968, Medtronic Inc., Minneapolis, MN, USA) were placed.

3.3. Device implantation and pacing mode

Fifty-two patients received pacemaker devices for atrial-synchronized biventricular pacing (Medtronic InSync System model 8040 or model 8042, Guidant Contak TR). In accordance with current ICD guidelines, 33 (38%) patients at high risk of sudden death received an ICD (Medtronic InSync ICD model 7272; Medtronic InSync II Marquis model 7289; Guidant Contak TR Renewal) and an endocardial shocking lead implanted in the RV. At the time of assessing the defibrillation energy requirement, patients were sedated intermittently with mask analgesia.

Pacing was delivered in biventricular DDD mode. Active pacing was selected by programming the atrial-synchronous mode with the atrioventricular (AV) delay determined by hemodynamic evaluation. In most cases the AV-delay was optimized based on Doppler echocardiography.

3.4. Statistical analysis

The proportion of patients with a given characteristic was compared by chi-square test. Differences between the means of the two groups were tested with Student's *t*-test. Normal probability plots showed that the treshold data had a non-normal distribution. Therefore, groups were compared using non-parameric methods (Mann-Whitney *U*-test). The standard deviation for threshold data was expressed in standard error of mean. Time-related and survival curves were constructed using the Kaplan-Meier

method (tested by Gehan's Wilcoxon test). Data analysis was performed with Statistica version 6 from StatSoft, Inc./USA.

4. Results

Since August 1999, LV pacing was achieved by positioning the pacing electrodes into a tributary of the coronary sinus venous system as method of first choice. This transvenous approach was used in 79 patients (CS-group). Of these, 9 patients needed to be converted to surgically placed epicardial LV-leads after failing CS-lead implantation. Seven patients received a surgical epicardial LV-lead placement as the primary approach in our unit. Therefore the LV pacing lead was inserted through a left-lateral mini-thoracotomy (7 ± 4 cm in length) accounting for a total of 16 patients (Epi-group). Mean follow up time was 16.4 ± 15.4 months, ranging from 0.1 month to 45 months representing 107.1 patient-years.

4.1. Intraoperative data

For the entire series mean QRS-duration decreased significantly from 182 ± 22 to 143 ± 16 ms ($P<0.001$) with no statistical difference between the groups. All mini-thoracotomy approaches ($n=16$) needed full anesthesia and intubation, whereas intubation deemed necessary only in 31 (39%) of the transcutaneous procedures (CS-group; $P<0.04$). Of these 31 patients only 6 (8%) patients needed full anesthesia, mainly because of agitation or anxiety in ICD implantation. Mean procedure duration (skin-to-skin) was 134 ± 38 min for LV-lead implantation through a mini-thoracotomy and 198 ± 62 min for placing a CS-lead ($P<0.03$). Total fluoroscopic time, including placement of the RA- and RV-leads, was 16 ± 12 min in the Epi-group, only needed for placing the RA- and RV-lead and 46 ± 23 min for the transvenous group ($P<0.05$). There was no contrast fluid used for mini-thoracotomy procedures, but in all patients to place the CS-lead (78 ± 69 ml; $P<0.001$). The preoperatively determined lead positioning [anatomically: area of the obtuse marginal branch of the circumflex artery (Epi-group); lateral, anterolateral or posterolateral tributary of the coronary sinus (CS-group)] was achieved in all surgical epicardial lead performances, but only in 55 (70%) transvenous CS-lead placements ($P<0.03$).

4.2. Acute and chronic left ventricular lead parameters

Acute LV-lead sensing did not significantly differ in both groups (CS-group: 14.2 ± 6.8 mV vs Epi-group: 13.6 ± 8.1 mV). During the follow up period there were no complications involving adjustment of pacemaker sensitivity in either group. Acute and chronic thresholds-capture of the LV-leads are shown in Fig. 3. Chronic threshold-capture was significantly lower in the Epi-group ($P<0.05$) in all controls. Acute threshold-capture during implantation of surgical epicardial LV-leads and CS-leads were 0.9 ± 0.5 V/0.5 ms and 1.1 ± 0.8 V/0.5 ms, respectively ($P=0.45$) At 18 months postoperatively, the threshold-capture of CS-leads increased to 2.2 ± 1.4 V/0.5 ms whereas it decreased for
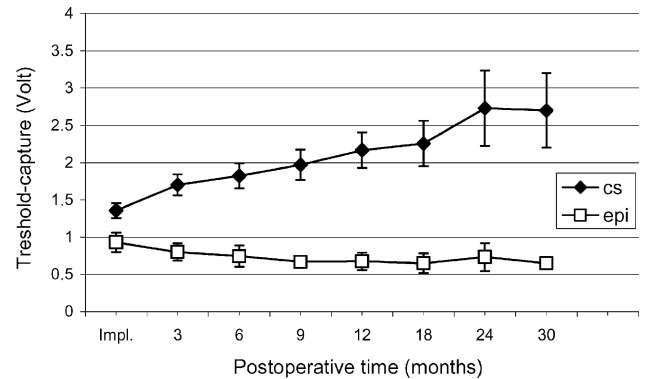

Fig. 3. Acute (Impl.) and chronic mean threshold-capture at a pulse width of 0.5 ms. for LV-leads implanted either in a tributary of the coronary sinus (CS) or surgically epicardial with mini-thoracotomy (Epi). Chronic threshold-capture of surgically placed LV-leads was in all controls significantly lower ($P<0.05$). The thresholds of the CS-group represents 70 patients, 9 patients had missing values; the Epi-group had complete follow-up.

surgical placed epicardial LV-leads to 0.7 ± 0.3 V/0.5 ms ($P<0.003$). At 18 months follow up 7 CS-leads had a threshold of >4 V/0.5 ms whereas all surgical epicardial LV-leads had a threshold under 1.1 V/0.5 ms, except for one (1.8 V/0.5 ms). The thresholds of the CS-group were available in 70 patients, 9 patients had missing values.

4.3. Length of hospital stay

Postoperative hospital stay tended to be longer for patients receiving surgically placed epicardial leads compared to transvenously placed CS-leads (11.6 ± 6.2 vs. 9.1 ± 6.4 days), probably reflecting our careful observation after this novel treatment-option. However, the difference was not significant ($P=0.18$).

4.4. Complications and mortality

During the follow-up period 43 (54%) complications related to the operation were reported in 35 patients of the CS-group. Of these, 18 (27%) events were unrelated to the implantation of the CS-leads. Most common were right atrial or right ventricular lead dislocation ($n=6$) and conversion to ICD-devices ($n=4$). Two pleural or cardiac effusions needed treatment and one pocket infection resulted in explantation of the CRT system. There were 25 (32%) LV-lead related complications in the CS-group: Eleven patients had a failed attempt to place the LV-lead in a tributary of the coronary sinus [dissection with termination of the procedure (2), inability to advance the lead to its final venous destination (3), failed implantation not specified (5) and one diaphragmatic stimulation]. In five of these patients, the second attempt was a surgical epicardial LV-lead placement, one CS-lead implantation was repeated in a later procedure, one patient received heart transplantation and 4 patients, refused a second attempt, receiving only a conventional dual chamber device. In another 4 patients dissection (one suspected) of the coronary sinus occurred, but CS-lead implantation could be completed successfully. The following complications were observed in the postoperative period: three unacceptably high pacing

thresholds with early depletion of the battery, three diaphragmatic stimulations and three lead dislodgements. The treatment consisted of CS-lead reimplantation in 4 patients, surgical placement of epicardial leads in three patients, CS-lead suspension in one patient. Two patients refused a correction of the LV-lead.

After surgical placement of a LV-lead, 6 (38%) complications related to the implantation of the devices were reported in 4 patients. Five (32%) events were unrelated to the implantation of the LV-lead: Two patients developed a pneumothorax without necessity of operative intervention. One patient experienced a right upper lobe atelectasis during intubation. Thus, the operation had to be postponed by four days. This patient and one other patient with pneumothorax were ventilated of more than 24 h, but no patient with CS-lead implantation ($P < 0.05$). One (6%) LV-lead related event (lead displacement) needed surgical refixation. Compared to CS-leads, the surgically placed LV-leads had significantly less LV-lead related complications ($P < 0.05$; Fig. 4).

In total, four patients underwent heart transplantation, all within 5 months after CRT. Nine patients (10.5%) died during the observation period (Fig. 5). One patient in each group died in the first 30 postoperative days. However, death was not related to the procedure: One cause of death in a patient after CS-lead implantation 13 days postoperatively was septic shock with consecutive multi-organ failure, most likely due to an infected femoral venous line. He suffered preoperatively from mitral valve regurgitation II–III, coronary disease, chronic atrial fibrillation and severe diabetes and was in NYHA IV. The other cause of death was in a patient after surgical lead implantation 28 days postoperatively for progressive heart failure (preoperative diagnosis: NYHA IV, mitral valve regurgitation IV). This patient had a failed CS-lead implantation as first CRT intervention. He needed refixation of the displaced surgically placed LV-lead,
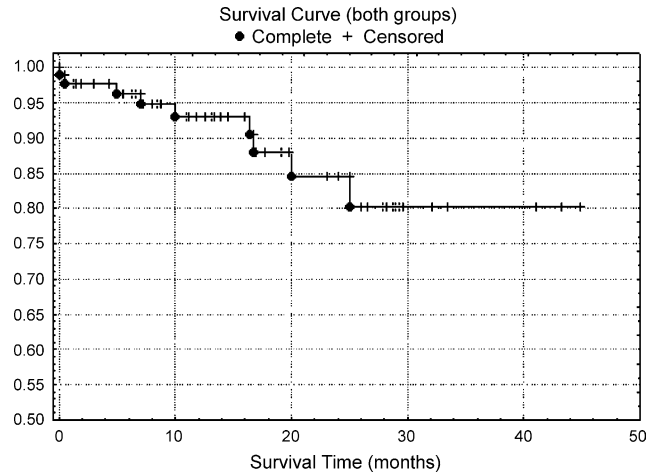
Fig. 5. Actuarial survival of the CRT-population ($n = 86$).

as already described above. Prior to CRT a mitral valve operation was refused because of his bad clinical condition.

There were 7 late deaths. Four patients died of cardiac reasons, of these, three had no ICD-device: one patient died of stroke during atrial fibrillation, one of sudden cardiac death, one after heart transplantation and one, listed for heart-kidney transplantation needed mechanical resuscitation for progression of heart failure and recurrent sepsis. Three patients died of non-cardiac reasons: one patient died of multi-organ failure, one of sepsis due to multiple central lines, and one of uncertain cause.

5. Discussion

The main focus of this study was to examine the technical aspects of the implantation of LV-leads for biventricular pacing. Looking back, LV stimulation was first achieved by surgical epicardial approach [10,12]. Currently, transvenous placement of the LV-lead via the coronary sinus is the first choice approach [1–5,9,10]. There has been a natural progression to transvenous placement of CS-leads due to the demand for less invasive procedures and more patient comfort. As long as there are no indications for an ICD-device, there is usually no need for intubation and general anesthesia to place the CS-lead. This is the major drawback of surgically placed LV-leads: Intubation and general anesthesia may lead to prolonged postoperative hospitalization. Daoud [10] and Izutani [13], similar to us, reported this issue in their thoracotomy-groups as well. However, in contrast to Daoud, in the thoracotomy-group of Izutani, Auricchio [3] and ours there was no significant increase of early mortality. Daoud and colleagues described a relatively high morbidity and early mortality (43%) in their thoracotomy group, but their multivariate analysis confirmed that the absence of spironolactone therapy, rather than the implantation technique was the sole feature associated with increased death. In addition, the higher exacerbation of the CHF in the thoracotomy group postoperatively could be impeded by catecholamine treatment. This again demonstrates that patients referred to surgery especially with advanced heart failure need optimized perioperative (drug-)
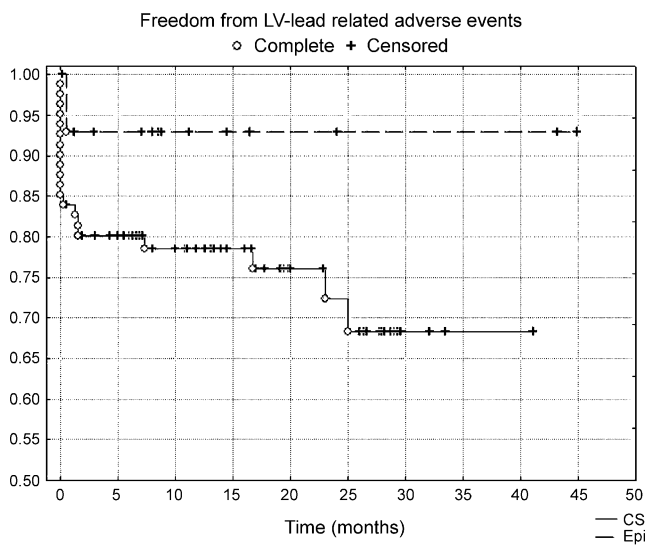

Fig. 4. Freedom from LV-lead related adverse events (Kaplan-Meier). Patients with surgically placed epicardial LV-leads had significantly less adverse events related to LV-lead implantation compared to the CS-lead group ($P < 0.05$). CS = patients ($n = 79$) with LV-lead implanted via the coronary sinus; Epi = patients ($n = 16$) with surgically placed LV-leads.

therapy to gain optimal postoperative outcome. In our study, many patients had long-lasting attempts to place coronary sinus leads with contrast fluid and in flat supine position prior to surgery, which also is cumbering the failing heart. This might have as well effects on the postoperative results.

Minimization of a procedure should not be associated with a decreased success-rate or negative affection of the outcome. In literature, failure rates and lead related complications of CS-leads are frequently described ranging from 0% to more than 50% after implantation to six or 12 months follow up [1,4,9,14]. In our series, we had 11 (14%) failed LV-lead implantations via the coronary sinus and 4 (5%) dissections without clinical evidence. In the follow up period of nearly 4 years, 8 patients experienced 9 (11%) CS-lead related complications, including three (4%) lead dislodgements. The MIRACLE trial (571 participating patients, enrolled from November 1998 till December 2000) [1] reports unsuccessful CS-lead implantations in 8% and dissection or perforation of the coronary sinus or cardiac vein in 6%. Serious adverse events, (complete heart block, hemopericardium and cardiac arrest) were observed in 1,2%. Two patients died due to the implantation within 30 days after the operation. Within 6 months follow up, 6% needed repositioning or replacement of the CS-lead. In total, the MIRACLE trial reports more than 21% CS-related adverse events within 6 months. After the first 1000 patients were enrolled in the European Contak Registry (www.guidant.com), approximately 150 (15%) of the patients had failed attempts to place the CS-lead. In 6 months follow up, 5% CS-lead related adverse events were seen. In a series of 102 patients, Reuter et al. [15] reported 13% unsuccessful attempts to place the CS-lead and 5% CS-lead interventions within 12 months due to dislodgement or CS-dissection. Fatemi et al. [9] reported of 7 (16%) failed CS-lead implantations, 6 (14%) dislodgements within the first 2 postoperative days and 5% diaphragmatic stimulations in a series of 43 patients implanted since 1999 and a follow-up of 6 months. In an earlier study, Gras et al. [16] enrolled 117 patients from August 1997 to November 1998. Fourteen patients (12%) were excluded from the study due to failed CS-lead implantation. Within a follow-up of 3 months, 10 patients experienced 13 dislodgments (13%) and within 12 month another 4 patients (4%) had CS-related complications (3 loss of pacing capture, 1 diaphragmatic stimulation). In another study, performed before 1999, Valls-Bertault et al. [17] excluded 7 (20%) failed CS-lead implantations from a series of 35 patients. He observed 3 (32%) lead dislodgements within the first 24 postoperative hours and another 4 (17%) out of 23 patients CS-lead related complications within the first 6 months.

Some reports do describe a very good success rate with CS-leads. Yu et al. [18] implanted a CRT-system in all 30 patients successfully via coronary sinus and reported no complications within the first 3 months. Best results in more than 100 patients were reported from Bad Oenhausen [19] with a success-rate of 99,1%. However, these reports are rare and reflecting not the average experience. As implantation systems via coronary sinus are complex, a learning curve can be expected. In large trials the implantation success has increased with experience and improvement of the equipment [20]. Reports with large study-cohorts about this fairly new treatment option of CHF with a follow up of more than 6 months are rare. Therefore, in most trials, CS-lead related complications like pacing threshold peaks, loss of pacing capture, diaphragmatic stimulation or coronary sinus thrombosis are probably not yet well documented. With regard to implantation failure rates, it seems that the over-the-wire implanted leads tend to be superior to the pre-shaped CS-leads [10]. Companies like Medtronic Inc. that offer both pre-shaped and over-the-wire leads, reported that at present nearly all procedures are performed with the over-the-wire technique (personal communication).

Our results of the epicardial placed LV-leads demonstrate a clear advantage regarding lead related complications and the necessity of reoperations. Surgical LV-lead placement offers the advantage of direct access to the lateral left ventricular wall. The direct visualization provides a nearly unrestricted opportunity of lead implantation to the optimal target site so that the determined lead position was achieved in all patients. In contrast, the determined position for the transvenously placed CS-leads were less successful. For anatomical or technical reasons it was often not possible to place the lead via coronary sinus and its tributaries to the target area where optimal concordance between the left ventricular pacing site and the site of most delayed left ventricular wall is achieved. This position is usually reached through a posterolateral vein. Some articles, which clearly stated the pacing site, report of a large proportion of patients that had a CS-lead implanted into an atypical site (i.e. anterior or middle cardiac vein). Alonso et al. reported of 36% atypically placed leads [21]. In a later experience positioning at intended target site (lateral, anterolateral or posterolateral tributary of the coronary sinus) was achieved in 70% [20]. Similar results were reported in the Easytrak Registry 2001: 54% reached lateral (including 10% questionable apical-lateral) and 13% posterior positions. In more than 30% the CS-leads were in an anterior position. Pacing the LV free wall obviously produces best results in hemodynamic response [12,22] while pacing the LV anterior wall has disadvantageous in hemodynamics [22]. Molhoek et al. [23] reported of 35% posterior and 28% lateral positioned CS-leads. In our series we experienced same results: 30% of all CS-leads could not be placed at the intended target site.

Another important finding in our series is the significantly increased long-term threshold-capture of CS-leads compared to epicardial placed LV-leads. This is consistent with most studies with long-term follow up. Alonso described a threshold of 1.9 ± 0.9 V/0.5 ms after mean follow up of 15 month. Similar experience is reported in the Easytrak Registry after 13 months follow up ($n=233$ patients). Early CS-lead models produced even higher thresholds, e.g. 3.2 ± 0.8 V/0.5 ms in some studies [17]. This might be due to limited access with the venous approach or a compromise position between determined optimal pacing site and best threshold position. We had 7 patients at 18 month follow up with a threshold-capture exceeding 4 V/0.5 ms. The higher need for pacing energy may result in early battery depletion.

In our series, surgical epicardial LV-lead placement was less time-consuming and had less fluoroscopy time. In addition, no contrast fluid was needed. These data are

analogous to those of Izutani et al. [13]. Daoud et al. [10], who had identical procedure durations in thoracotomy and CS-lead approach, placed a second LV-lead in the thoracotomy group for safety reasons, which in our experience is not necessary with the steroid-eluting Medtronic model 4695. It is of utmost importance to place the LV-lead in the optimal target site. However, to determine this position best is still under investigation as the pathophysiology behind CRT is complex and modern mapping procedures itself may prolong the procedure. Therefore, time consuming LV-lead placement attempts should be avoided. In our opinion, LV-lead placement through coronary sinus exceeding 2 h should be discontinued and surgically placed. Conventional dual chamber pacing in failed CS-leads is unacceptable for this patient group as well, especially for those with very long QRS duration, because worsening of patient's condition is possible, e.g. development of severe mitral valve regurgitation. However, in accordance with most investigators, the implantation procedure for CRT needs technical improvements for both surgical and coronary sinus approaches. In the past, industry had concentrated most efforts on developing CS-leads, but CS-lead implantation is still challenging and the industry shows latterly growing interest in developing minimally invasive surgical methods. At present, most promising seems to be the thoracoscopic approach with the malleable 10626 Epicardial Lead Implantation Tool (Medtronic Inc., MN), launched last year. The implantation tool enables a reduction of the operative trauma without compromising optimal lead placement [11]. Furthermore, advancements and prototypes of the next generation of surgical epicardial leads are already in progress. At first glance, robotically enhanced LV-lead implantations seemed to be exaggerated, but some have demonstrated good results with minimal access. In addition, Derose [24] placed his patients in full posterolateral thoracotomy position for robotic approach. This improved access to the intended target area of the left posterolateral wall. However, the widespread in daily practice is unlikely due to limited access to robotic systems.

Three of 4 patients in our study, who died of cardiac reasons, had no ICD device and 4 received a conversion to ICD treatment in the follow up. This data attaches value to the COMPANION trial, which showed highest reduction (43%) in all-cause mortality for heart failure patients combining CRT and defibrillator [2,7,25]. On the other hand ICD treatment dramatically increases the costs of this procedure, facing the fact that 5 million patients in the United States and 1.3 million patients in Germany suffer from congestive heart failure. Many of these are not sufficiently improved by drug therapy. Approximately 30% of cardiomyopathy patients have an intraventricular conduction delay exceeding 120 ms so that CRT seems an treatment option in these patients. Some trials already demonstrated a decrease of hospitalization [1,5]. It is important to state that identification of patients that will most likely benefit from CRT is still not clear and it is still an open issue to identify non-responders to CRT. Four patients in our study received heart transplantation soon after CRT. Many CRT-patients also satisfy criteria for heart transplantation. Heart transplantation provides good long-term outcome and so far, there is no prospective randomized trails that compare benefits of CRT and heart transplantation.

6. Conclusion

Transvenous placement of the LV-lead via the coronary sinus is the first choice approach. Nevertheless, surgical placed epicardial leads revealed excellent long-term results and a lower LV-related complication rate compared to CS-leads. Although, the approach via limited thoracotomy for biventricular pacing is associated with 'more surgery', it is a safe and reliable technique, offers 100% lead positioning at intended target area and might have potential benefits as primary implantation for a substantial subset of patients.

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Appendix A. Conference discussion

Mr P. Totaro (*Swansea, UK*): In the first slide you showed that, despite the fact that with the epicardial leads you can choose the best position, there was a statistically significant difference in the mean QRS which was in the patients with epicardial leads still 177. How can you explain that?

Dr Mair: Mean QRS was in both groups 180 ms preoperatively and decreased significantly to 140 ms postoperatively. The QRS was not statistically different between the groups.

Dr F. Mohr (Leipzig, Germany): Your talk was very surgically orientated, does not reflect the real world, even if we want it going in this direction. I do have a question.

Did you do any measurements intraoperatively to really define the optimal place for lead implantation, because just saying it is easier and we can do it in 5 min will not define the real benefit? We do have the chance to really map the heart by echo, and if so, if we want to go for an intraoperative application through surgery, there must be something more than you showed, I have to say.

Dr Mair: Measuring of correct lead position is a key point in this procedure, independent if coronary sinus or surgical epicardial lead placement. At the beginning we placed it after mapping was performed pre- and intraoperatively by cardiologists, but we started doing intraoperative mapping for optimal ventricular lead placement. There are two approaches. First, the electrical evaluation: A simple method for locating optimal lead placement site. It identifies the site of latest left ventricular electrical activity following a paced ventricular beat. Second, we also started mechanical evaluation with intraoperative echocardiography. But as we started cardiac resynchronisation therapy four years ago mapping procedures improved and therefore we adapted and changed the mapping procedures.

Dr Mohr: Did you use transesophageal echo in those cases?

Dr Mair: We used it in most cases, currently in all.

Dr C. Khazen (Vienna, Austria): I want just to know how you decide to place the epicardial lead. Was there unsuccessful placement in the venous coronary? How did you analyze your patients?

Dr Mair: From 16 patients with epicardial leads, 9 patients were converted to surgical approach because of failing cs-lead in our hospital. From the other seven, 3 came to our department after the cs-approach failed in other units. We started with CRT 4 years ago and the first 4 were implanted surgical.

Dr Khazen: And this failure was after the learning curve or at the beginning of your experience?

Dr Mair: What do you mean, learning curve for the coronary sinus implantation?

Dr Khazen: Yes.

Dr Mair: As it is a four-years observation, of course the cardiologists and we went through a learning curve. In large studies like MIRACLE or COMPANION, a failure rate or a nonresponder rate of nearly 30% was as well described. Of course, the devices improved and our skill as well. But still, I think epicardial lead placement is a very good option.

Dr Khazen: With that do you mean that with the epicardial lead there are nonresponders?

Dr Mair: What do you mean?

Dr Khazen: The 30% nonresponders, 30%, that is in the literature. In the epicardial lead, you do not see it?

Dr Mair: The problem is, that the mapping strategy changed and improved in our procedures according to the recommendations of the literature. Therefore, from technical point of view we should not have any nonresponders when surgical implanted, but due to non-optimized mapping at the beginning and other reasons of chronic heart failure we have nonresponders. But a bigger patient group is necessary to define the rate of nonresponders.

Dr Khazen: Thank you.

Dr L. Bockeria (Moscow, Russia): I think that this is a point of interest for many of us and it will be widely investigated, I am sure, because, really, when having such a method like mapping, we can be very precise and I guess almost a hundred percent successful if we go strictly in this way.