

Biventricular pacing demonstrates similar effects in elderly and younger patients with advanced heart failure in the mid-term follow-up

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Abstract

Background: Biventricular (BIV) pacing has been shown to improve haemodynamics and functional status of patients (pts) with advanced chronic heart failure (CHF). No study has determined the effects of BIV in relation to the age of pts.

Aim: To compare the clinical outcome in two groups of pts: ≥ 65 yrs and < 65 yrs referred for BIV pacing in our centre with at least 6 months of follow-up.

Methods: Among 15 pts ≥ 65 yrs and 16 pts < 65 yrs successfully implanted with a BIV pacemaker, 12 and 15 pts, respectively, completed 6-month follow-up. Evaluation included change of NYHA class, 6-minute walking distance (6-minWD), drug therapy, QRS duration and echocardiographic parameters. The need for hospitalisation due to the worsening of CHF symptoms, assessed 6 months before and 6 months after BIV pacing, was compared. During long-term follow-up survival and complications related to this therapy were analysed.

Results: In both groups after 6 months of BIV pacing clinical improvement was observed, as demonstrated by the reduction in NYHA class ($p < 0.005$), average duration of hospitalisation due to CHF ($p < 0.05$) and diuretics doses ($p < 0.05$). The comparison of changes in these parameters between the two groups, as well as of changes in 6-minWD and echocardiographic parameters, did not show significant difference. BIV pacing enabled an increase in the dosage of beta-blockers (in 50% pts ≥ 65 yrs and 60% pts < 65 yrs), as well as of ACEI or ARB (25% and 40% pts, respectively). Survival was 80% in 15 pts ≥ 65 yrs during 16 ± 15 months of follow-up and 81% in 16 pts < 65 yrs during 22 ± 14 months. All complications occurred in the 30-day post-operative period with similar frequency in both groups, also when LV lead-related complications were compared.

Conclusions: In the mid-term follow-up BIV pacing demonstrates similar improvement in clinical status and exercise tolerance in elderly pts ≥ 65 yrs, as compared with pts < 65 yrs. In both groups BIV pacing reduced the need for hospitalisation due to worsening of CHF symptoms, and enabled beneficial changes in the pharmacological treatment. Elderly patients are not at risk of more frequent complications associated with BIV pacing.

Key words: heart failure, cardiac resynchronisation therapy, biventricular pacing

Kardiologia Polska 2006; 64: 975-983

Introduction

The results of large randomised clinical trials such as MIRACLE [1], MIRACLE ICD [2], Contak CD [3], COMPANION [4] and the recent CARE-HF trial [5] have shown that biventricular pacing (BIV) improves clinical

condition, exercise capacity and the quality of life of selected patients with advanced systolic heart failure. Additionally to the improvement of haemodynamic parameters, these trials also confirmed beneficial left ventricular (LV) remodelling and improvement of LV

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Received: 17.06.2005. **Accepted:** 31.05.2006.

function. Two recent large trials, COMPANION [4] and CARE-HF [5], showed significantly better prognosis and survival of patients with BIV pacing.

In the next years this approach is expected to further develop and spread, especially as chronic heart failure (CHF) is becoming a more common health problem, particularly in the highly developed countries. It is undoubtedly favoured by the lengthening of lifetime and ageing of the population. The incidence of CHF in the Framingham Heart Study among males aged 50-59 years was 8 per 1000 and increased up to 66/1000 males aged 80-89 years. Similar results were obtained for females – 8 and 79/1000 females, respectively [6]. Ageing of societies increases the number of patients with CHF. Mean growth of CHF incidence within 1989-1999 was 1/1000 and 0.9/1000, respectively, for females and males. From 1971 to 1999 it was associated with almost a 4-fold increase in hospitalisation rate for worsening of CHF [7]. It was also found that at least 20% of hospitalisations of patients over 65 years were due to CHF [8].

Therefore, it may be predicted that older patients will comprise a considerable proportion of subjects treated with BIV pacing. No study has determined the effects of resynchronisation therapy with respect to patient age so far. This study presents the outcomes of BIV pacing in 15 patients aged ≥ 65 years and 16 younger subjects, i.e. < 65 years, with advanced CHF treated at our site.

Methods

Patients and study protocol

In our department BIV pacing was used in patients with dilated cardiomyopathy, impaired LV function (ejection fraction $\leq 35\%$) and disturbances of intraventricular conduction (QRS ≥ 120 ms), in whom enhanced symptoms of CHF (NYHA III/IV) persisted despite optimal pharmacological therapy. Also NYHA class II or II/III patients with indications for implantable cardioverter-defibrillator (ICD) and echocardiographic signs of ventricular mechanical systolic dyssynchrony were qualified for implantation. The latter was also diagnosed if the interventricular mechanical delay (IVD) was ≥ 35 ms.

Patients' clinical condition and pharmacological treatment were also assessed. Furthermore, hospitalisation times due to worsening of CHF before and after implantation were compared. Changes in selected echocardiographic parameters were also analysed. The results were compared between the two following groups of patients: ≥ 65 years and < 65 years. Moreover, the selected parameters measured at baseline and after BIV pacing system implantation were compared between groups. Patient survival and implantation-related complications were evaluated during long-term follow-up. Before and after the implantation procedure as well as at

3 and 6 months later standard 12-lead ECG was performed (at paper speed of 50 mm/sec) to check pacing effectiveness and QRS duration.

Implantation procedure

The LV pacing lead was transvenously introduced under fluoroscopy via the subclavian vein through the coronary sinus to the selected epicardial vein (the lateral cardiac vein was preferred to the posterolateral and anterolateral veins). The remaining BIV system leads were placed into the auricle of the right atrium (RA) and the right ventricle (RV).

Echocardiography methods

The studies were carried out using Sonos 2000 (Hewlett-Packard) and a 2.0-3.5 MHz probe. Left ventricular ejection fraction (LVEF) was calculated with Simpson's method using four and dual chamber apical views. Interventricular mechanical delay was defined as presystolic time difference at the level of aortic and pulmonic valves. Changes of analysed echocardiographic parameters (2D and Doppler mode) were assessed by comparing the results of echocardiography performed before the implantation and after 6-month BIV pacing. The results were compared between the two age groups ≥ 65 years and < 65 years, and changes in the analysed parameters were compared between groups.

Clinical assessment

The studies involved patients with BiV pacing and at least 6-month follow-up. All patients had their clinical condition evaluated, before the implantation and after 3 and 6 months of BIV pacing, including determination of NYHA functional class and 6-minute walking distance (6-minWD). Six-minute walking test was performed according to the guidelines of the American Thoracic Society [9]. Pharmacological treatment was analysed, with special stress on dosage of diuretics, angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB) and β -blockers. Increase of betablocker or ACEI and ARB was defined as implementation of new therapy with these drug classes or previous dose increase by at least 50%. The results were compared between the two groups of patients: ≥ 65 years and < 65 years. The need for hospitalisation due to worsening of CHF was also assessed in both groups 6 months before and 6 months after BIV pacing onset. Additionally, changes in analysed parameters between groups were compared.

Statistical analysis

Arithmetic mean and standard deviation were calculated for individual parameters. Significance of differences between constant variables was confirmed using Student's t-test or variance analysis, and between

Table I. Baseline demographic and clinical characteristics of patients treated with BiV pacing with respect to age of patients: ≥ 65 years and < 65 years

| Variable | Group ≥ 65 yrs (N=15) | Group < 65 yrs (N=16) | p |
|--|----------------------------|-------------------------|--------|
| Age [years] | 71 \pm 3 (66-76) | 55 \pm 8 (40-63) | <0.001 |
| Gender: males/females [number] | 13/2 | 13/3 | NS |
| Arrhythmias [number of patients/percentage]: | | | |
| • Paroxysmal atrial fibrillation | 4 (27) | 1 (6) | NS |
| • Persistent atrial fibrillation | 4 (27) | 3 (19) | NS |
| • Ventricular tachyarrhythmias: | 5 (33) | 8 (50) | NS |
| – Ventricular tachycardia | 5 (33) | 6 (38) | NS |
| – Ventricular fibrillation | 1 (7) | 2 (13) | NS |
| Comorbidities [number of patients/percentage]: | | | |
| • Ischaemic cardiomyopathy | 11 (73) | 10 (63) | NS |
| – Past myocardial infarction | 5 (33) | 5 (31) | NS |
| – Status post PCI of CABG | 7 (47) | 7 (44) | NS |
| • Idiopathic dilated cardiomyopathy | 4 (27) | 6 (38) | NS |
| • Arterial hypertension | 5 (33) | 5 (31) | NS |
| • Atrio-ventricular conduction abnormalities | 3 (20) | 5 (31) | NS |
| • Diabetes mellitus | 2 (13) | 4 (25) | NS |
| • Chronic obstructive pulmonary disease | 2 (13) | 0 | NS |
| Pharmacologic treatment [number of patients/percentage]: | | | |
| • ACEI | 11 (73) | 12 (75) | NS |
| • ARB | 2 (13) | 2 (13) | NS |
| • β -blockers | 10 (67) | 16 (100) | <0.05 |
| • Furosemide | 14 (93) | 16 (100) | NS |
| • Spironolactone | 8 (53) | 14 (87) | <0.05 |
| • Digoxin | 8 (53) | 10 (62) | NS |
| NYHA class | 3.2 \pm 0.6 (2-4.0) | 3.0 \pm 0.4 (2-3.5) | NS |
| QRS duration [ms] | 179 \pm 34 (150-240) | 181 \pm 36 (130-230) | NS |
| Left ventricular ejection fraction [%] | 22 \pm 5 (14-30) | 25 \pm 4 (20-32) | NS |
| Left ventricular end-diastolic diameter [mm] | 72 \pm 7 (62-84) | 72 \pm 7 (61-84) | NS |
| Interventricular mechanical delay [ms] | 44 \pm 19 (35-80) | 45 \pm 15 (25-80) | NS |
| Follow-up period [months] | 16 \pm 15 (1-54.5) | 22 \pm 14 (3-54.5) | NS |

Abbreviations: PCI – percutaneous coronary intervention, CABG – coronary artery bypass grafting, ACEI – angiotensin converting enzyme inhibitors, ARB – angiotensin receptor blockers

qualitative variables using χ^2 or McNemara tests. Confidence level of 95% and a p value < 0.05 were considered significant.

Results

Patients

The BiV pacing system was implanted in 15 patients ≥ 65 years and in 16 subjects < 65 years. Median age of patients in the two groups was 70.6 and 58.5 years, respectively. Dual chamber ICD was implanted in patients with indications for ICD therapy

(5 and 8 individuals, respectively). Clinical characteristics of the participants are presented in Table I. There was no difference between groups with respect to aetiology and severity of CHF, comorbidities and medical treatment apart from betablockers and spironolactone, which were more often used in younger patients.

Implantation

Implantation of the BIV pacing system was successful and uncomplicated in all patients. The pacing system was implanted previously in 5 older patients (VVI – 2, DDD – 3)

Table II. NYHA class, 6-minute walking distance (6-minWD) and mean daily furosemide dose (mg per patient) before BiV pacemaker implantation and during follow-up visits in the two study groups: 12 patients aged ≥ 65 years (A) and in 15 patients < 65 years (B)

| A. Patients aged ≥ 65 years | | | | | | |
|----------------------------------|------------------------|-------------------------|------------------------|--------|--------|---------|
| Variable | Values | | | p | | |
| | Before implantation | 3 month BIV pacing | 6 month BIV pacing | 0 vs 3 | 3 vs 6 | 0 vs 6 |
| NYHA class | 3.2 \pm 0.5 (2-4) | 2.6 \pm 0.4 (2-3.5) | 2.6 \pm 0.5 (2-4) | <0.005 | NS | <0.005 |
| 6-minWD [m] | 254 \pm 134 (48-392) | 280 \pm 154 (50-560) | 316 \pm 124 (0-448) | NS | NS | NS |
| Furosemide daily dose [mg] | 98 \pm 95 (40-360) | 80 \pm 98 (40-360) | 69 \pm 95 (0-320) | NS | NS | <0.05 |
| B. Patients aged < 65 years | | | | | | |
| Variable | Values | | | p | | |
| | Before implantation | 3 month BIV pacing | 6 month BIV pacing | 0 vs 3 | 3 vs 6 | 0 vs 6 |
| NYHA class | 3 \pm 0.4 (2-3.5) | 2.3 \pm 0.6 (1-3.5) | 2 \pm 0.6 (1-3) | <0.001 | <0.001 | <0.0001 |
| 6-minWD [m] | 327 \pm 134 (50-540) | 393 \pm 131 (120-650) | 467 \pm 174 (156-75) | <0.01 | <0.01 | <0.01 |
| Furosemide daily dose [mg] | 104 \pm 65 (40-240) | 87 \pm 58 (40-240) | 65 \pm 44 (40-200) | NS | <0.1 | <0.05 |

Table III. Comparison of changes (Δ) of NYHA class, 6-minute walking distance (6-minWD) and mean daily furosemide dose (mg per patient) in both groups of patients (older, n=12 and younger ones, n=15) after implantation of BiV pacing system

| Variable | Patients ≥ 65 years | Patients < 65 years | p |
|-----------------------------------|--------------------------|-----------------------|----|
| NYHA class | | | |
| $\Delta 3$ months – 0 | -0.6 \pm 0.5 | -0.7 \pm 0.6 | NS |
| $\Delta 6$ months – 3 months | -0.04 \pm 0.5 | -0.2 \pm 0.3 | NS |
| $\Delta 6$ months – 0 | -0.6 \pm 0.7 | -0.9 \pm 0.6 | NS |
| 6-minWD [m] | | | |
| $\Delta 3$ months – 0 | 27 \pm 176 | 36 \pm 185 | NS |
| $\Delta 6$ months – 3 months | 35 \pm 146 | 105 \pm 177 | NS |
| $\Delta 6$ months – 0 | 62 \pm 93 | 140 \pm 157 | NS |
| Furosemide daily dose [mg] | | | |
| $\Delta 6$ months – 0 | -29 \pm 40 | -41 \pm 66 | NS |

and in 5 younger patients (VVI – 1, DDD – 1, DDDR – 3). One patient from the younger group had a dual chamber ICD implanted previously. In these subjects an LV lead was inserted, while previously implanted RA and RV leads remained intact.

Clinical assessment

Scheduled 6-month follow-up was completed by 12 patients from the group aged ≥ 65 years and by 15 patients aged < 65 years. Three older patients (1 – failed reposition of LV lead, 1 – death on 15 day post procedure and 1 with follow-up below 6 months) and one patient

from the younger group (elective heart transplant performed 2.5 months after BiV pacing system implantation) were excluded from the analysis.

Following implantation of the BiV pacing system, a decrease in CHF symptoms was observed and a significant reduction of NYHA class was noted in both groups after 3 months. After 6 months device therapy the improvement was still present in the older patients, whereas it was prominent in the younger ones compared to a 3-month time period (Table II). Statistically significant prolongation of 6-minWD, after both 3 and 6 months of BiV pacing, was observed only in younger patients (Table II). Despite more spectacular improvement in younger patients differences of NYHA class 6-minWD changes (Δ) between the groups failed to reach statistical significance (Table III).

In the majority of patients diuretics doses could be incrementally reduced and after 6-month BiV pacing individual furosemide daily dose was significantly lower (Table II); however, no difference between the study groups was seen (Table III). Also the proportion of patients receiving furosemide did not significantly differ between the groups (Table IV). The increase of β -blockers and ACEI or ARB dosage was possible in both groups. β -blocker dose was increased in 50% of older and 60% of younger patients, whereas ACEI or ARB dosage was increased in 25% and 40% of patients, respectively (NS, Table IV).

Echocardiographic parameters

After 6 months of BiV pacing, LV, RV and LA parameters did not change significantly in either group in comparison to the values registered prior to the

Table IV. Pharmacological treatment before implantation and after 6 months of BiV pacing in the two studied groups (% of patients receiving individual agents is presented)

| Drug | Before implantation | | After 6 month BiV pacing | | P | |
|--------------|---------------------|-----------|--------------------------|-----------|-----------|-----------|
| | ≥65 years | <65 years | ≥65 years | <65 years | ≥65 years | <65 years |
| Furosemide | 91 | 100 | 83 | 100 | NS | NS |
| ACEI or ARB | 91 | 100 | 100 | 100 | NS | NS |
| Spirolactone | 66 | 70 | 50 | 78 | NS | NS |
| Digoxin | 66 | 74 | 58 | 74 | NS | NS |
| β-blockers | 58 | 100 | 83 | 100 | NS | NS |

Abbreviations: see Table I

Table V. Results of echocardiography performed before BiV pacemaker implantation and after 6 months of BiV pacing in the two studied groups

| Variable | Patients ≥65 yrs | | | Patients <65 yrs | | |
|------------|---------------------|--------------------------|--------|---------------------|--------------------------|-------|
| | Before implantation | After 6 month BiV pacing | p | Before implantation | After 6 month BiV pacing | p |
| LVEDD [mm] | 72±7 (62-84) | 68±9 (59-82) | NS | 72±7 (61-84) | 66±7 (62-82) | NS |
| LVESD [mm] | 60±9 (48-75) | 61±8 (44-76) | NS | 6.1±0.8 (42-72) | 5.6±0.8 (43-69) | NS |
| LVEF [%] | 22±5 (14-30) | 26±7 (18-33) | NS | 25±4 (20-32) | 29±3 (25-35) | <0.05 |
| LA [mm] | 53±7 (41-65) | 54±7 (41-68) | NS | 5.3±0.8 (40-67) | 5.2±0.8 (40-63) | NS |
| RV [mm] | 29±6 (18-48) | 3.1±0.5 (28-37) | NS | 3.3±0.6 (18-48) | 3.4±0.5 (29-44) | NS |
| IVD [ms] | 44±21 (10-80) | 26±23 (10-50) | <0.001 | 45±15 (25-80) | 33±18 (15-35) | NS |

LVEDD – left ventricular end-diastolic diameter, LVESD – left ventricular end-systolic diameter, LVEF – left ventricular ejection fraction, LA – left atrium diameter, RV – right ventricular diameter, IVD – interventricular mechanical delay

procedure. Significant increase of LVEF from 25±4% to 29±3% ($p < 0.05$) was noted in younger patients, while it showed no considerable variation in the elderly group. In both groups significant shortening of IVD was confirmed and the change was more marked in older subjects (Table V). Comparison between the two study groups regarding the absolute changes in the echocardiographic parameters, however, showed no significant differences (Table VI).

QRS duration

Mean QRS duration before pacing system implantation in the older group was 179±32 ms (150-240 ms) and after the procedure was 172±19 ms (150-220 ms). These measurements were significantly diverse in the younger group and equalled 181±36 ms (120-221 ms) and 169±27 ms (120-200 ms), respectively. Change of QRS width following BiV pacing was not significant in either group and did not change significantly over the follow-up.

Hospitalisations before and after BiV pacing onset

Hospitalisation rate due to worsening of CHF decreased in both groups after implantation. Mean in-hospital stay required due to CHF for patients aged

Table VI. Comparison of changes (Δ) of the echocardiographic parameters assessed after 6 months of BiV pacing in the two studied groups

| Variable | Patients ≥65 years | Patients <65 years | p |
|---------------------|--------------------|--------------------|----|
| Δ LVEDD [mm] | -6±7 | -5±7 | NS |
| Δ LVESD [mm] | 0±8 | -5±8 | NS |
| Δ LVEF [%] | 4±5 | 5±5 | NS |
| Δ LA [mm] | -0.4±7 | -1.4±6 | NS |
| Δ RV [mm] | -0.9±4 | -1.8±6 | NS |
| Δ IVD [ms] | -17±30 | -17±15 | NS |

Abbreviations: see Table V

≥65 years during 6-month surveillance prior to implantation was 19±16 days (0-56 days), whereas within the first 6 months of BiV pacing it was reduced to 5.3±10 days (0-31 days) ($p < 0.05$). It was 3.9±9 days (0-26 days) in patients aged <65 years vs 18±12 days before the procedure (5-55 days, $p < 0.01$). Shortening of period of hospitalisation for worsening of CHF was similar in both study groups: -14±19 days in older vs -15±4 days in younger ones (NS).

Complications

All complications occurred within the 30-day post-procedural period. Frequency of complications, including those associated with the LV lead, was similar in both groups. Complications were observed in 6 (40%) of 15 patients aged ≥ 65 years, being associated with implantation of LV lead and requiring reoperation in 4 (27%) patients. In the entire group of 16 patients aged < 65 years complications occurred in 8 (50%), including 7 (44%) subjects with complications regarding the LV lead and 5 (31%) patients in whom revision of the pacing system was required.

In 3 older individuals dislocation of LV lead into the right ventricle was observed. Successful reposition of leads was carried out in all patients. In one subject qualified for dual chamber ICD, BIV pacing threshold increased > 7.2 V/1.0 ms, which resulted in loss of resynchronisation. In this case LV lead reposition failed and eventually ICD was implanted with only right ventricular pacing. Pneumothorax occurred in 1 patient and was treated with passive chest drainage. In one female subject infective endocarditis was diagnosed 20 days after the procedure and was effectively treated with targeted antibiotics.

Among younger subjects one had LV lead displacement into the right ventricle, and in 4 others the LV lead was displaced within the target coronary vein, which considerably elevated the LV or BIV pacing threshold. Lead reposition was successful in all cases. A non-serious complication was pocket haematoma after pacemaker implantation in one patient; it was treated conservatively. Phrenic nerve stimulation observed in another patient was eliminated by decrease of LV pacing amplitude. Another patient with BIV-ICD underwent four VT episodes on the second day post implantation which recurred on the following days despite adjustment of pharmacologic treatment (so-called electric storm). Adequate programming of ICD allowed for removal of the proarrhythmic effect of LV pacing.

Patient survival

In the entire group of 15 subjects aged ≥ 65 years, 3 patients died during mean 16 ± 15 months of follow-up. One patient died on the 15th day post implantation due to stroke and 2 other subjects due to the progression of CHF at the 7th and 24th month after implantation of the device. Survival in this group was 80%.

In the group of 16 patients aged < 65 years one subject died during mean 22 ± 14 months of follow-up 16 months after the procedure due to progression of CHF. Elective heart transplantation was performed in 2 other patients (after 2.5 and 12 months). Survival of younger patients was 81%.

Discussion

The results of our study show that in mid-term follow-up BIV pacing may also be beneficial for older patients with advanced CHF and impaired interventricular conduction and this effect is similar to that observed in younger patients. In both groups BIV pacing resulted in improvement of clinical condition as well as reduction of hospitalization duration due to worsening of CHF, and allowed doses of diuretics to be decreased; the changes were similar in older and younger patients. Decrease of CHF symptoms expressed with NYHA class and improvement of physical capacity as measured by means of 6-minWD were also similar in the two studied groups.

In the studied groups the percentage of patients with coronary artery disease was comparable. In the literature there are still doubts regarding aetiology of CHF in the context of results of BIV pacing. The majority of papers show the same benefits for patients with ischaemic cardiomyopathy as well as idiopathic dilated cardiomyopathy [4, 10]; however, there exist reports on worse outcomes in patients in whom severe CHF has an ischaemic basis [11].

It should be noted that the age of the elderly group (median 70.6 years) treated with BIV pacing is older than in large randomised clinical trials. In CARE-HF [5] median age was 67 years and patients aged > 70 years made up 34%. MIRACLE [1] involved patients at mean age of 64 ± 11 years, while in COMPANION [4] median age of patients treated with BIV pacing was 67 years and with additional ICD implantation it was 66 years. Studies completed so far such as COMPANION [4] and CARE-HF [5] have highlighted the poorer advantages of BIV pacing in older patients compared to younger ones. However, follow-up duration was longer than in our study, which presents mid-term follow-up outcomes.

We have also observed that during 6-month follow-up decrease of CHF symptoms was not connected with significant changes of heart chamber sizes or LV function assessed on echocardiography. We did indeed record significant improvement of LVEF in younger patients after 6 month pacing but LVEF changes did not differ between the study groups. In this context it would be interesting to compare the results of echocardiographic studies of our patients after 12-18 months of BIV pacing therapy.

We also found that BIV pacing led to a decrease in the incidence of CHF exacerbations that required hospitalisation and these benefits were similar in both groups. Our observations remain consistent with the results of other trials such as MIRACLE [1], MUSTIC [12], COMPANION [4] and CARE-HF [5]. For example, in the MIRACLE study [1] the percentage of hospitalisations during a 6-month period decreased from 15% to 8%

and mean number of days spent in hospital decreased from 363 to 83.

This information also has an important economic aspect. Reduction of the number of hospitalisations of patients with CHF, a group in which expenses related to in-hospital treatment of exacerbations constitute more than 60% of medical costs [13], is very desirable. It is essential that such benefits can be shown not just for younger patients but also for the elderly CHF group and as early as after 6 months of therapy. Moreover, it was proven that, exactly owing to a significant reduction of hospitalisations, the expensive cost of BIV pacemakers pays off within half a year following implantation [14].

In the majority of studied patients doses of diuretics could be reduced, which is consistent with reports of other investigators and results from better renal filtration due to improvement of LV function caused by BIV pacing. The benefits of this phenomenon are related to, among other things, possible risks connected with this class of medicines, especially for older patients. Additionally, β -blocker doses were increased in both groups (in 50% of older and 60% of younger patients); also ACEI or ARB could be increased (in 25% and 40% of patients). Being aware of the valuable effects of these drugs for CHF therapy, the prospect of optimal adjustment of therapy after implantation of the BIV pacing system remains further advantage for CHF patients.

Survival in both study groups was equally high bearing in mind the poor prognosis of patients with CHF and NYHA class III-IV [15]. Survival was 80% in 15 patients aged ≥ 65 years during mean 16 ± 15 month follow-up period and 81% in 16 patients aged < 65 years during 22 ± 14 months. The beneficial influence of BIV pacing on the reduction of risk of death in CHF patients was verified by the COMPANION and CARE-HF trials. In the latter one [5], as compared with medical therapy alone, cardiac resynchronisation reduced the risk of cardiovascular death or hospitalisation by 37% vs 55% (hazard ratio: 0.63; 95% CI: 0.51-0.77; $p < 0.001$).

Periprocedural complications were not present in any of our patients and all first-time implantations were successful. However, later complications were observed in both groups and all within the first 30 days following implantation. Frequency of complications was similar in the two groups, including problems related to LV lead placement. The most common adverse event was dislocation of the LV lead (moving into the right ventricle or its displacement within the cardiac vein resulting in marked increase of LV pacing threshold and ineffective resynchronisation). Undoubtedly, this complication was observed more often in our study group than in other cited trials. These results may be interpreted as the *learning curve effect* regarding this

approach in our site but it was also affected by the accessibility of LV pacing leads and coronary sinus cannulation kits. This was widely discussed in our other report on problems and failures of BIV pacing [16].

In conclusion, the outcomes of BiV pacing in older patients are promising as leading to significant improvement in their clinical condition and symptoms of CHF. It is worth mentioning that this specific group of subjects is not among heart transplantation recipients. Certainly it would be interesting to enrol more patients and extend the follow-up period.

Conclusions

1. In the mid-term follow-up BiV pacing demonstrates similar improvement in clinical condition and exercise tolerance in both elderly patients ≥ 65 years and younger patients with advanced CHF and disturbances of intraventricular conduction.
2. Biventricular pacing leads to reduction of hospitalisation for worsening of CHF in older (≥ 65 years) and younger patients (< 65 years).
3. Biventricular pacing enables beneficial adjustment of medical therapy: reduction of diuretics and increase of beta-blockers and ACEI in both younger and older patients.
4. Cardiac resynchronisation therapy in patients aged ≥ 65 years was not associated with higher incidence of adverse events than in younger subjects.

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Stymulacja dwukomorowa przynosi podobne korzyści w obserwacji średnioterminowej u starszych i u młodszych chorych z zaawansowaną niewydolnością serca

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Streszczenie

Wstęp: Stymulacja dwukomorowa (BIV) prowadzi do istotnej poprawy parametrów hemodynamicznych, funkcji lewej komory (LV), tolerancji wysiłku oraz jakości życia u wybranych pacjentów z zaawansowaną niewydolnością serca (CHF). Jak dotąd nie analizowano efektów takiego leczenia w zależności od wieku chorych.

Cel: Porównanie wyników zastosowania stymulacji BIV u pacjentów w wieku ≥ 65 lat i < 65 lat leczonych w naszym ośrodku.

Metody: Układ BIV implantowano u 15 chorych ≥ 65 . roku życia i u 16 < 65 . roku życia. Badaniami, które obejmowały ocenę stanu klinicznego, dystansu 6-min marszu (6-minWD), stosowanej farmakoterapii, czasu trwania zespołów QRS oraz parametrów echokardiograficznych, objęto odpowiednio 12 i 15 pacjentów z przynajmniej 6-mies. okresem obserwacji po zabiegu. W obu grupach porównano czas hospitalizacji z powodu zaostrzenia CHF w ciągu 6 mies. przed implantacją oraz 6 mies. po zabiegu. W obserwacji odległej analizowano przeżywalność chorych oraz występowanie powikłań.

Wyniki: Po 6 mies. stymulacji BIV w obu grupach odnotowano istotną poprawę kliniczną: redukcję klasy wg NYHA ($p < 0,005$), zmniejszenie czasu hospitalizacji z powodu CHF ($p < 0,05$) oraz dobowej dawki furosemidu w przeliczeniu na jednego pacjenta ($p < 0,05$). Porównanie zmian tych parametrów, jak również 6-minWD oraz parametrów echokardiograficznych pomiędzy grupami nie wykazało istotnych różnic. W obu grupach możliwe było zwiększenie dawki β -blokerów (u 50% starszych i 60% młodszych chorych), a także ACEI lub sartanów (odpowiednio u 25% i 40%). W czasie 16 ± 15 mies. obserwacji przeżywalność w grupie 15 chorych ≥ 65 . roku życia wynosiła 80% oraz 81% w grupie 16 osób w wieku < 65 lat w czasie 22 ± 14 mies. Wszystkie powikłania wystąpiły w okresie pierwszych 30 dni po zabiegu i ich częstość była podobna w obu grupach, w tym powikłań związanych z implantacją elektrody LV.

Wnioski: W obserwacji średnioterminowej stymulacja BIV przynosi podobną poprawę stanu klinicznego i tolerancji wysiłku u starszych i u młodszych pacjentów z zaawansowaną niewydolnością serca i zaburzeniami przewodzenia śródkomorowego. W obu grupach możliwe było zmniejszenie czasu hospitalizacji z powodu CHF, a także korzystna modyfikacja terapii farmakologicznej. Podeszły wiek pacjentów leczonych stymulacją BIV nie wiąże się ze zwiększonym ryzykiem występowania powikłań.

Słowa kluczowe: niewydolność serca, stymulacja resynchronizująca, stymulacja dwukomorowa

Kardiologia Pol 2006; 64: 975-983

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Praca wpłynęła: 17.06.2005. Zaakceptowana do druku: 31.05.2006.