Clinical and Technical Aspects of Permanent BiA Pacing Using Standard DDD Pacemaker - Long-Term Experience in 47 Patients

A. KUTARSKI, T. WIDOMSKA-CZEKAJSKA, K. OLESZCZAK, M. WÓJCIK, K. POLESZAK
Dept. of Cardiology, University Medical Academy, Lublin, Poland

Summary

The most popular mechanism for multisite atrial pacing remains split BP (bipolar) configuration. Some years ago (when "Y" connectors were not available) we began using BiA pacing with the system proposed by Osterholzer and Markewitz in 1988. In 47 patients with recurrent arrhythmias, RAA leads were connected to the atrial port and the CS lead to the ventricular port of a standard DDD pacemaker. During examinations, the RAA (progr. AAI), CS (progr. VVI), and both atria (progr. DDD with AV=15 ms) were paced; the last one was then left as permanent. Acute CS sensing parameters were slightly worse (A ampl. 2.8 mV; slew rate 0.8 V/s) than in the RAA (respectively 3.5 mV and 1.1 V/s,) but during follow up (FU) a slight improvement of CS sensing was noted. T wave was never sensed and there were no problems with V wave sensing in the CS channel as well. Acute values of PTh were lower in the RAA (BP 0.6 V; UP 0.5 V) than in the CS (respectively UP 3.3 and BP 2.4 V). Values of PTh in the RAA were highest after one month (average 1.6 V) and decreased during the next month. The same evolution of PTh during FU, but on a higher level was observed in the CS. Impedance in both channels showed an increasing tendency during FU. CS pacing appeared to be a markedly higher energy consumer (about 18 µJ) than standard RA pacing (about 4 µJ): global current drain during BiA pacing remained acceptable (about 35 µA). Clinical effects generally were satisfactory. Spectacular success (without arrhythmias, without drugs) occurred in 12 patients (26%), satisfactory success (no recurrence, but AA drugs used and rare recurrence together with AA drugs used) was in 18 patients (38%). Five patients (11%) required additional surgery due to LA arrhythmias; technical problems with resynchronization, arrhythmia recurrence or permanent AF was observed in 11 patients (23%). After two years of FU we found good functionality of the pacing system in 33 out of 47 patients. Four patients were in AF, but in that periode before AF started efficient biatrial (BiA) pacing was available. Antiarrhythmic effect in 10 patients at the end of FU could not be evaluated because they received different pacing systems or remained paced for RAA only. AV conduction disturbances developed in 2 patients nearly at the end of the FU period. The main advantages of a BiA pacing system seem to be precise (separate for each atrium) output programming (energy saving), sensing of atria in BP configuration (lower V amplitude sensing), maintenance of atrial pacing in case of dislocation/exit-block of CS lead, and the possibility of separate evaluation of CS pacing/sensing conditions. Its disadvantages include the inability of V pacing if A-V block occurs and the inability for resynchronized pacing during premature LA excitations. CONCLUSIONS: 1) BiA pacing is a very promising mode for suppression of atrial arrhythmias, 2) BiA pacing using a DDD pacemaker is the simplest solution, but the risk of appearance of LA arrhythmias and AV conduction disturbances remain its main limitations.

Key Words

Biatrial pacing, atrial arrhythmias, follow-up

Introduction

The role of intra/interatrial conduction disturbances (IACD) were recognized as important and common factors in recurrent atrial arrhythmias (e.g. typical and atypical forms of atrial flutter and fibrillation) many years ago [1-5]. Since 1994, multisite resynchronized atrial pacing modes created new therapeutic options for patients on both sides of the Atlantic (Rennes and New York). Daubert proposed biatrial (BiA), and Saxena dual site right atrial pacing configurations [6,7]. The results of studies conducted by both research groups proved to be very promising [4,5,8-12]. Fifty to sixty percent of patients remained free of arrhythmias and drug intervention, in 20-30%, the frequency of recurring arrhythmias decreased significantly, and in 20-30% of patients resynchronized pacing did not influence the recurrence of arrhythmias, or patients showed permanent atrial fibrillation (AF).

Until now, a special pacemaker for BiA pacing (with a double atrial port) has not been readily available on the market, and the most popular device for BiA pacing remains a split bipole (BP) configuration [4-11,13-19]. In this unique configuration the "Y" connector connects the cathode to the standard right atrial UP lead, and connects the anode to the second atrial lead (with the tip located in the ostium of the coronary sinus (CS) or mid CS (rarely proximal or distal CS) [13-29]. This pacing/sensing configuration permits for excellent sensing of both atria, and excellent resynchronized pacing (if the AAT program is applied) during sinus rhythm and with premature ectopic beats originating from the right or left atrium as well [13,17-29]. Disadvantages of the split BP configuration (electrodes connected in series) result in a high global impedance and secondary to them - a relatively high pacing threshold (PTh) [13,17-29].

Inspired by Daubert's and Saxena's promising results, 3 years ago we started using BiA pacing (with standard leads and pacemakers) in patients with severe and frequent drug resistant atrial arrhythmias [13,30-35]. At the time,"Y" connectors were not available to us, so we decided to implant resynchronized systems described by Markewitz and Osterholzer in 1988 [36,37]. The authors described utilizing the standard DDD pacemaker (with AV delay programmed as short as possible) for the resynchronization of donor and recipient atria in patients following orthotopic heart transplantation and sinus node insufficiency. The lead implanted to the atrial remnant was connected to the atrial port, and the other one implanted into the right atrium (RA) of the transplanted heart - to the ventricular port of the DDD pacemaker. The recipient atrium served as a sensor and the VDD (with short AV delay) program enabled restoration of the chronotropic function of the transplant if the recipient sinus chronotrophy was preserved [36,37].

Review of the literature suggested that no one had tried to use both channels of the standard DDD pacemaker for BiA pacing during this time. From September 1996 to September 1997, we implanted the (Markewitz and Osterholzer) resynchronized BiA pacing system into

Patients	No.: 47, male: 21, female: 26, age: 51-88 (average: 69.3)					
Arrhythmias	atrial flutter	14		recurrent* (1/week<1/mth)		21
				frequent or incessant >1/week/daily		21
	atrial fibrillation	34		after persist AF		3
				after chronic AF		2
Operation	primary implanted BiA pacing system		29	pacemakers:	Dromos	12
	change of pacing mode	A(RA)->BiA	16		Physios	25
		D(RA)->BiA	2		Eikos	10
Leads	RA leads:	TiJ 53 BP	19	CS leads:	TIR60BP	24
		SX 53 BP	10		SD60BP	4
		PX 53 BP and other	18		SX60BP	5
					V182,202,203	14

Table 1. Number of patients, clinical history of the patients and pacing hardware.

47 patients and the preliminary results were promising [13,30-34]. Disadvantages of the Markewitz/Osterholzer pacing system are recognizeable, but their is a "Y" connector available (Biotronik A1 CS SB); maybe with new possibilities of implantation of other configurations for BiA pacing.
The aim of this study was to present our experiences with the clinical and technical aspects of long term BiA pacing using the standard DDD pacemaker.

Methods

Patient selection
For BiA pacing we selected a group of 47 patients who met the following criteria:

- Classical indications for permanent pacing due to BRT syndrome with episodes of sinus arrest (32 patients) and/or a drug- induced bradycardia (11 patients) and/or episodes of slow ventricular rate during treatment of atrial arrhythmia (18 patients).
- Inter/intra-atrial conduction disturbances (IACD) with sinus (29 patients) or paced (18 patients) PII-wave duration over 125 ms. The degree of IACD was verified during CS lead implantation (AAT over 160 ms) and no false positive primary diagnosis was found.
- Drug-resistant symptomatic atrial arrhythmia (flutter or fibrillation) with recurrence more than once per month (see Table 1). All patients were usually treated two or more times per month for atrial arrhythmias in HDR (hosp. day regimen). Due to atrial arrhythmias, 18 out of 47 patients were previously permanently paced from RA (15 patients) or only CS (3 patients), and in all of them single site atrial pacing significantly increased IACD.
- Absence of AV disturbances in their history and Wenckebach greater than 130/min.

Atrial arrhythmias
Fourteen patients suffered from typical atrial flutter (AFl) and another 33 experienced atrial fibrillation, documented on an ECG before DC cardioversion. In most patients, analysis of the Holter monitor indicated the presence of short episodes of Afl, and finally we could suspect that in part of this group of patients, AF-recorded after several hours/days during admission to hospital could be degenerated into AFl. ECG and Holter picture strongly suggested that left atrial (LA) premature excitations preceded episodes of atrial arrhythmia in 10 patients and an inverted lead connection was then applied.

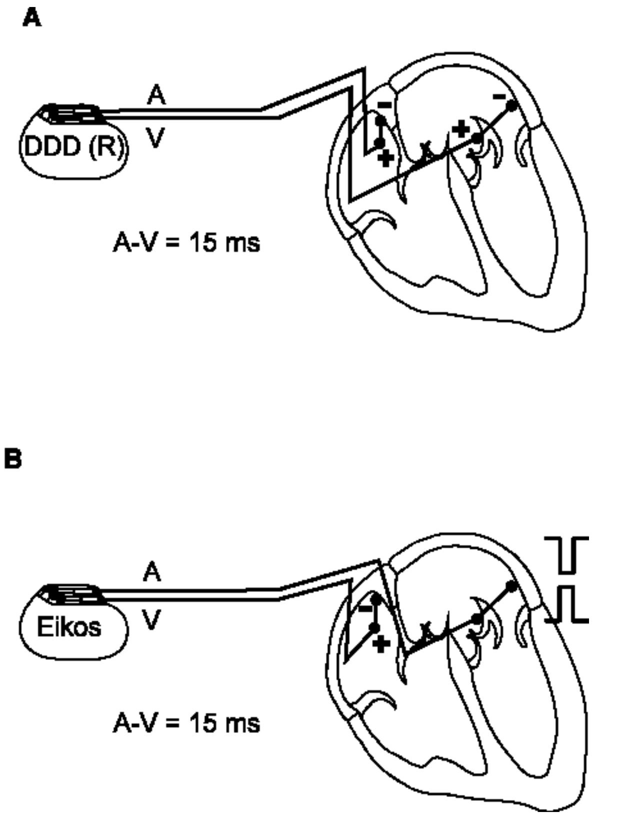

Figure 1. BiA pacing system with standard DDD pacemaker: A) Classical connection of leads. VDD (or DDD) program with ultra short AV delay enables resynchronized pacing of LA during sinus rhythm, and RA premature ectopic beats. Resynchronization of LA premature excitation is impossible. B) Inverted connection of leads. Applied overlapping biphasic pacing improves the effectiveness of LA pacing. VDD (or DDD) with a relatively high frequency program, enables resynchronization only during paced rhythm or premature LA ectopic beats. Resynchronization of sinus and ectopic RA rhythms is impossible.

Pacing systems
Standard "J"- shaped bipolar (BP) leads, classically implanted in the right atrium appendage (RAA), were connected to the BP atrial port of a standard DDD pacemaker. Standard straight ("ventricular") BP leads were implanted in the CS mid position, and 1 to 3 tines were removed for better contact of the lead tip with the CS wall (33 patients) [13,20,25,30,34,36,39]. In other cases we used specially designed Biotronik leads

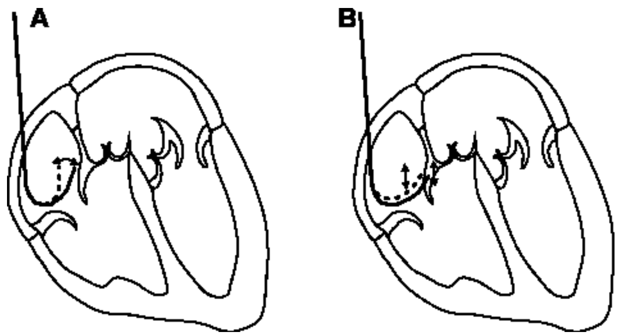

Figure 2. Characteristic movement of the distal part of the leads shows location of its tip: A) The horizontal movement (right « left) of the tip indicates its anterior direction (lower appendage region). B) The vertical (up « down) movement indicates its posterior direction (coronary sinus region).

(14 patients); the CS lead was usually connected to the ventricular BP port of the same pacemaker (37 patients) (Biotronik: Dromos DR-12 and Physios 01 or TC 01-25) [13]. In 10 patients with predominant LA arrhythmias, we used inverted connections for more effective (OLBI) CS pacing (Eikos SLD pacemakers) [34,40].

Pacemakers

For simultaneous pacing of both atria using standard DDD pacemakers, we selected the Dromos (DR) and Physios (01 or TC 01) models (Biotronik) due to the possibility of programming an ultra- short AV delay (15 ms) and the excellent telemetry possibilities (including filtered IEGM transmission). We avoided using the Actros (shortest AV delay = 50 ms) and Logos (filtered IEGM transmission not available) families instead, we preferred using BP CS devices with better pacing and sensing conditions [13,30,38-40]. We had to use BP RA leads for avoidance of "electrode conflict" during DDD pacing in the BP configuration (Dromos and Physios families). Some patients with old, but still functioning UP RA leads were selected to use other BiA pacing systems (with split bipoles) [13,20,22,25-28].

Implantation of Leads

RAA and CS leads were introduced into the venous system using the standard procedure of puncturing the subclavian vein. Lead tips were located using PA X-ray fluoroscopy. All 47 CS lead implantation procedures were successful, due to our previous experience in implanting over 100 leads [13,25,30,39]. X-ray fluoroscopy time ranged from 1-20 min, and in half of the patients did not exceed 10 min. Occasionally it exceeded 15 min. The implantation procedure for standard and special CS leads was the same. The first step was to position the lead tip in the lower part of the RA using a straight stylet. The second step was to position the lead tip in the CS ostium using a wide "J"- (more "L") shaped stylet (formed by hand). The lead tip was directed to the backbone and the CS ostium was usually located in the left part of its shadow in the lower part of the tricuspid annulus (refer to enclosed X-ray photos). Careful observation of the movements of the lead tip were very helpful in finding the CS ostium (see

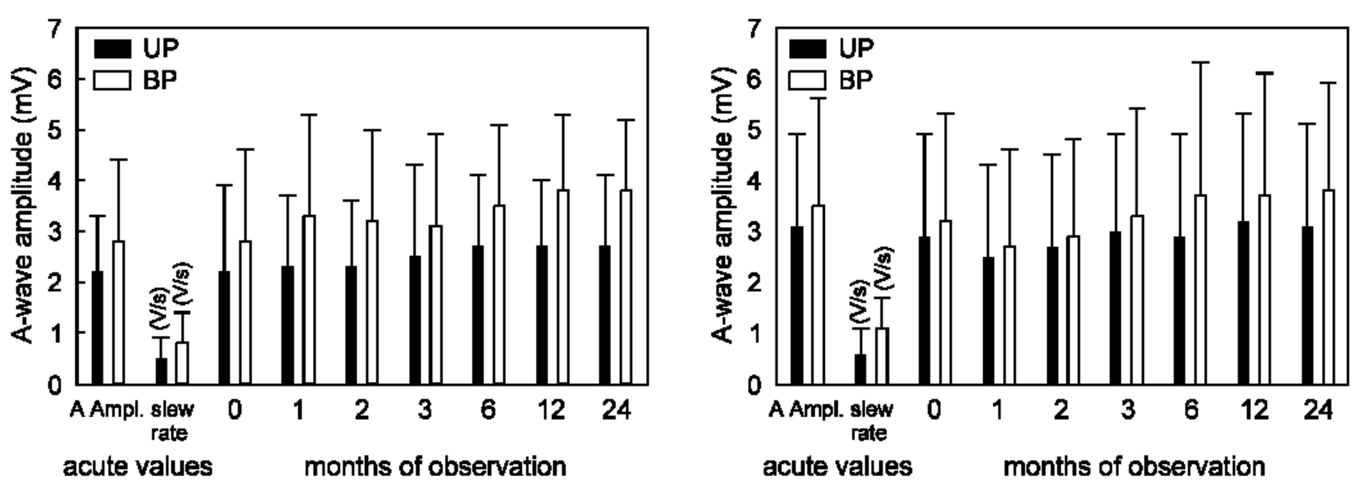

Figure 3. Acute and follow-up sensing data in the RAA and coronary sinus.

Figure 2). The third step was insertion of the lead into the CS. During this procedure only the lead was moved; deeper insertion of the stylet was only possible when the lead tip exceeded only half of the CS length. We found the lowest PTh values if the proximal ring was not that far from the CS ostium [13,25,30,39]. This confirms earlier and later [41,42,43,44] results obtained by other authors.

Acute pacing and sensing conditions after final leads fixation were evaluated using the standard Biotronik pacing threshold analyser ERA 300.

Follow-up

Controls of the pacing/sensing conditions in the short and long term postoperative periods were performed via telemetry using the programmer PMS 1000 (Biotronik). The first examination was done 3-5 days after the operation while the patient was still in the hospital. The next set of controls were performed monthly for the next 6 months. After this period, follow-ups (FU) were repeated every 3 months. During FU, patients were questioned regarding the exact number of recurring arrhythmias, the restoration mode of the sinus (paced) rhythm, unknown heart palpitations (which were confirmed using the Holter pacemaker function) and antiarrhythmic therapy.

Results

Sensing conditions

The results of acute, subacute and chronic sensing conditions in patients with implanted BiADDD pacing systems were obtained, and the values are shown in Figure 3.

The acute sensing parameters in the coronary sinus (in BP configurations) were acceptable (average A wave amplitude 2.8 mV; slew rate 0.8 V/s), but markedly worse than in the RAA (respectively 3.5 mV and 1.1 V/s). During FU, slight improvement of CS sensing (increase average and median amplitude of A wave) was noted. Both atria were sensed during the whole observation period in the (BP) sensing program configuration. The unipolar sensing (UP) program was temporarily applied only during the control examination. It is important to note that the T wave was never sensed in the CS channel, and signs of its presence were never recorded in the IEGM. The QRS complex (V wave) was evaluated on paper IEGM records and the amplitude was similar or only slightly lower than

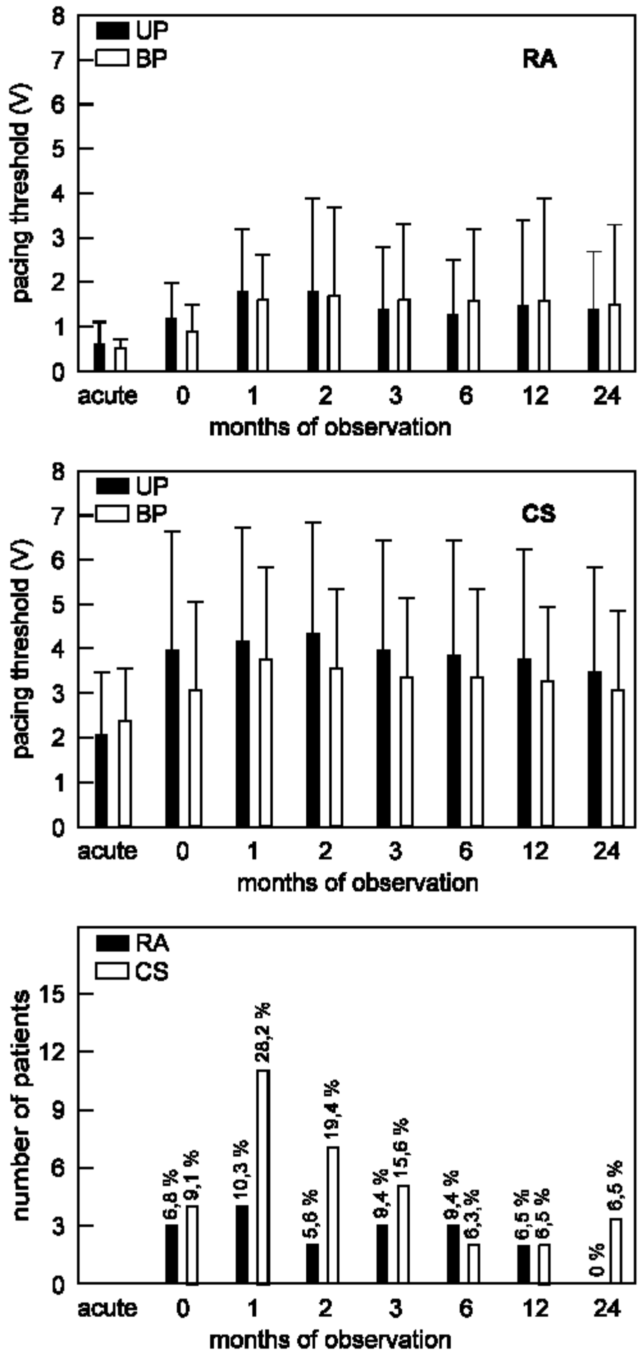

Figure 4. Acute and follow-up pacing data in the RAA and coronary sinus.

the amplitude of the LA A wave in most patients. There were not any problems with V wave sensing in the CS channel; programming of the refractory period even to 425-450 ms (in patients with prolonged AV conduction) permitted for avoidance of V wave sensing. On the other hand, CS pacing significantly shortened the atrial spike (QRS interval) and prevented additional V sensing-related problems [31-34,39,40].

Sensing problems

Unexpectedly, we observed slightly more frequent difficulties with sensing the RA, rather than LA A wave, due to its low amplitude. In 2 out of 4 patients, only the RA premature beats were not sensed. No additional surgery was necessary, and the problems were solved by programming a high sensitivity and "overdrive" rate. Programming of the "hyperchronotropic" sensor rate was the best solution. During real BiA pacing using a DDD pacemaker, sensing of the LA A wave played a minor role. LA originating premature excitations can not execute simultaneous RA pacing, and the very important resynchronisation can not be obtained if classical lead connections (CS lead connected to V channel) are applied. This condition was observed in 5 of the patients which were primary included in the group with RA arrhythmias and all were re-operated during the two-year FU period (split BP configuration was used).

Pacing conditions

Acute, subacute and chronic PTh values (measured with the ERA 300 pacing threshold analyser), as well as lead impedance and energy consumption (obtained with telemetry using the PMS 1000 programmer) are presented in Figures 3, 4 and 5.

Figure 4 shows average (SD) and median PTh values in the present group of 47 patients with a BiA pacing system.

Acute PTh values were significantly lower in the RAA (average BP 0.6 V; UP 0.5 V) than in the CS (UP 3.3 and BP 2.4 V, respectively). PTh values in the RAA were highest after one month (average 1.6 V) and decreased significantly during the next month (median value: 1.3 V after 1 month and 0.7 V after 2 years). The same tendency of evolution of PTh during FU, but on a different, higher level was observed in the CS (respectively median values of PTh decreased from 3.6 V to 3.3 V during long term observation).

Pacing problems

RAA pacing problems were noted in several patients: 2 of them needed high pacing energy and 2 with stable microdislocation of the lead were finally re-operated on successfully. LA pacing problems were more frequent, and were observed in 11 patients; exit block (PTh over 6.0 V/ 1.0 ms) disappeared spontaneously in 5 patients, 4 patients had dislocated CS leads which were successfully repositioned in other operations, but 2 patients had operations performed after nearly two years, due to unacceptable energy consumption (inverted hybrid split BP configuration was applied) [13,20,22,25-28,35].

Table 2 summarizes the reasons for subsequent operations in the observed group of patients. The most frequent cause of additional surgery was standard lead

				No. of patients	%
Good pacing, sensing, resynchronisation during whole 1 year follow-up				36/47	76.6
Reoperated during follow-up	the same pacing system	CS lead dislocation	standard leads	4/33	12.1
			CS designed leads	0/14	0.0
			total	4/47	8.5
		RA lead "micro-dislocation" (exit block)		2/47	4.2
	changed pacing system	CS exit block		2/47	4.2
		surgical problems		1/47	2.1
		LA arrhythmias, impossible resynchronisation		5/47	10.6
	total		no. of problems	13/47	27.6
			no. of pts	11/47	23.4
			permanent AF	4/47	8.5

Table 2. Problems and results of the implanted leads and pacing systems

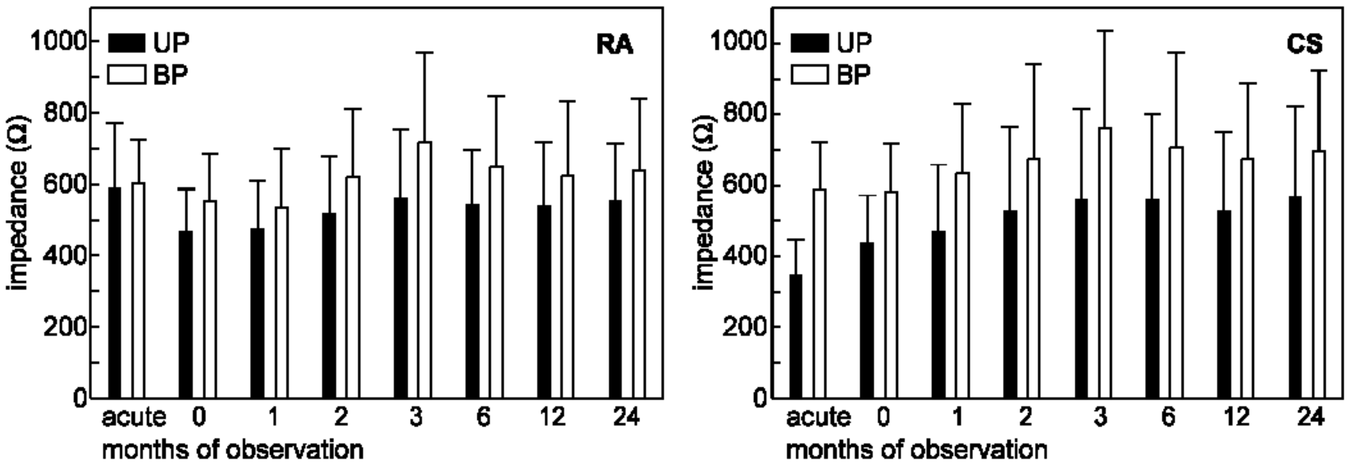

Figure 5. Acute and follow-up impedance data in the RAA and coronary sinus.

dislocation (12%), as well as the inability to resynchronize LA-originating arrhythmias. The frequencies of other indications for subsequent operations were comparable with other standard procedures.

Impedance and energy consumption

Figure 5 presents average and median values of impedance evaluated during implantation of leads and during long-term observation as well.

Average and median values of impedance showed a slightly increased tendency during long term FU. This effect was only slightly expressed in the RA (increased about 40-50 ohm), and more visable in the CS, especially in the BP configuration (increase of about 50-60 ohm). Marked differences of impedance in BP configurations are noted between the RA and the CS (about 50 ohm).

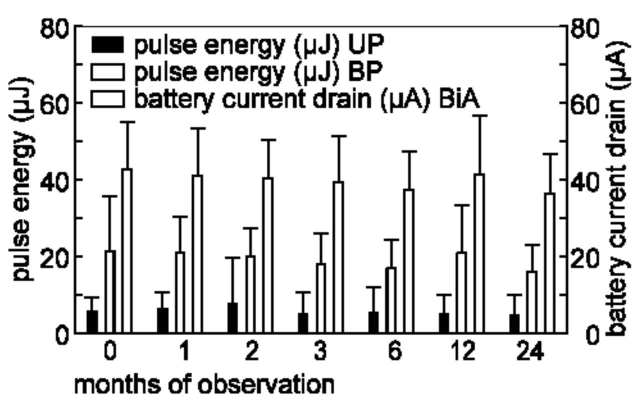

Figure 6. Energy consumption during biatrial pacing.

The information about the differences and trend of impedance values were helpful in interpreting energy consumption during BiA pacing using the DDD pacemaker. This is presented in Figure 6.

This table shows the values of energy consumption (in μJ) in channels (atrial or ventricular) connected with the RA and CS leads and total current drain from the battery (in μA). Permanent CS pacing shows markedly higher energy consumption (about 18 μJ) than standard RA pacing (about 4 μJ). Global current drain during BiA pacing remains acceptable (about 35 μA) but is more than 2-3 times higher than during standard DDD (RA and RV) pacing.

Clinical effects of BiA (DDD) pacing - two year follow-up

Table 3 summarized the 47 implanted BiA (DDD) pacing systems and their antiarrhythmic effects during a two year FU period.

After two years of FU, we found good functionality of the BiA (DDD) pacing system in 33 out of 47 patients. At the end of FU, 4 patients were in AF. In all 4 patients (2 with irreversible and 2 with reverted AF) efficient BiA pacing was possible before AF started. At the end of FU, the antiarrhythmic effect of BiA (DDD) pacing in 10 patients could not be evaluated, because they received different pacing systems (8 pts) or were paced from the RAA only. AV conduction disturbances (Wenckebach block) developed in 2 patients near the end of FU. Asymptomatic Wenckebach block made atrial pacing over 65-70/min impossible and limited the use of antiarrhythmic drug treatment.

BiA (DDD) pacing system functionality after 2 years F-U			No. of pts. (% of total pts/ 47)	% in group with working system (37pts)	final effect	
pts reached end point 2 y FU (still working pacing system)	well working BiA (DDD) pacing system. Antiarrhythmic effect in 37 pts	excellent	24 (51.1)	64.9	satisfactory	30/37 (81.1%)
		good	6 (12.8)	16.2		
		week	1 (2.1)	2.7	not satisfactory	7/37 (18.9%)
		no effect	2 (4.3)	5.4		
		permanent AF	4 (8.5)	10.8		
pts out of 2 y FU - another pacing system	CS exit block - only RA pacing		2 (4.3)		loss of BiA (DDD) pacing system	10/47 (21.2%)
	changed pacing system: BiA (DDD)->BiA (SBP)	LA arrhythmias	5 (10.6)			
		A-V block	2 (4.3)			
	surgical problems - expl. of pacing system		1 (2.1)			

Table 3. Clinical results of the 47 implanted biatrial (DDD) pacing systems at the end point of 2 years of follow-up. Excellent: no arrhythmia recurrence, no antiarrhythmic therapy; maximal 1 drug prophylactically. Good: sporadic arrhythmia recurrence; minor use of antiarrhythmic drugs without any severe consequence for the patient; significant less frequent hospitalisation neccessary due to arrhythmic recurrences. AF is efficiently reduced (periods/ duration). Week: still arrhythmia recurrence; repeated cardioversions, anticoagulation, two or more antiarrhythmic drugs have to be used regularly. No effect: no influence on AF recurrence.

Both patients received additional ventricular leads, "Y" connections and different lead connections (three-chamber pacing system with split BP-BiA pacing configuration), but in both of them a good antiarrhythmic effect of BiA pacing was previously observed.

Discussion

Until now BiA-designed pacemakers were not available, and three main modes of lead connections enabled successful BiA pacing using standard pacemakers.

The oldest one, described by Osterholzer and Markewitz used two channels of the DDD pacemaker for "simultaneous" (limitation: possibility of ultra short AV programming) pacing of both atria [36,37]. The second system was introduced in Rennes in 1990 by Daubert and later by Saxena in New York [45,5,7,8]. In this unique, never before used pacing system, both atrial leads are connected in a series (split); the cathode is connected to the RA and the anode to the CS lead. Advantages of these pacing configurations are relatively low energy consumption in spite of moderate high PTh values, and good sensing conditions. Disadvantages of the proposed system are anodic (potentially pro-arrhythmic) pacing of the LA, and risk of high impedance-related problems (two lead tips in the same circuit) [46,47]. The third lead connection system, primarily proposed by Caseau (for permanent BiV pacing), is based on parallel connections of leads and the cathode current via "Y" connector "divided" between two leads [17]. Advantages of these pacing configurations are relatively low pacing threshold, very low global lead impedance, and avoidance of potential pro-arrhythmic high energy anode current pacing. Similarly, splitting bipolar configurations (for BiA pacing only in the atrial channel of a DDD pacemaker) are used and there are no technical problems with ventricular pacing if necessary. The main disadvantage of this lead connection is the relatively high energy consumption. The current flow via each atrial lead inversely depends on impedance, but is not a local energy requirement. In cases of a mid/high PTh in the CS, a high pacemaker output has to be programmed and a lot of energy is wasted in the RA. The capacitor of the atrial channel of a standard pacemaker cannot be programmed to guarantee voltage in extreme situations [21,23,24,27-29,35].

Some years ago "Y" connectors were not popular on the market and we decided to start using BiA (DDD) pacemakers with the Osterholzer/Markewitz configuration (inverted or not). Special CS-designed leads were not available during our beginning experiences, so we started using standard straight BP leads (with the tines removed) for CS pacing [13,20,25,30,34,36,39]. Only the last 14 patients who received the CS-designed

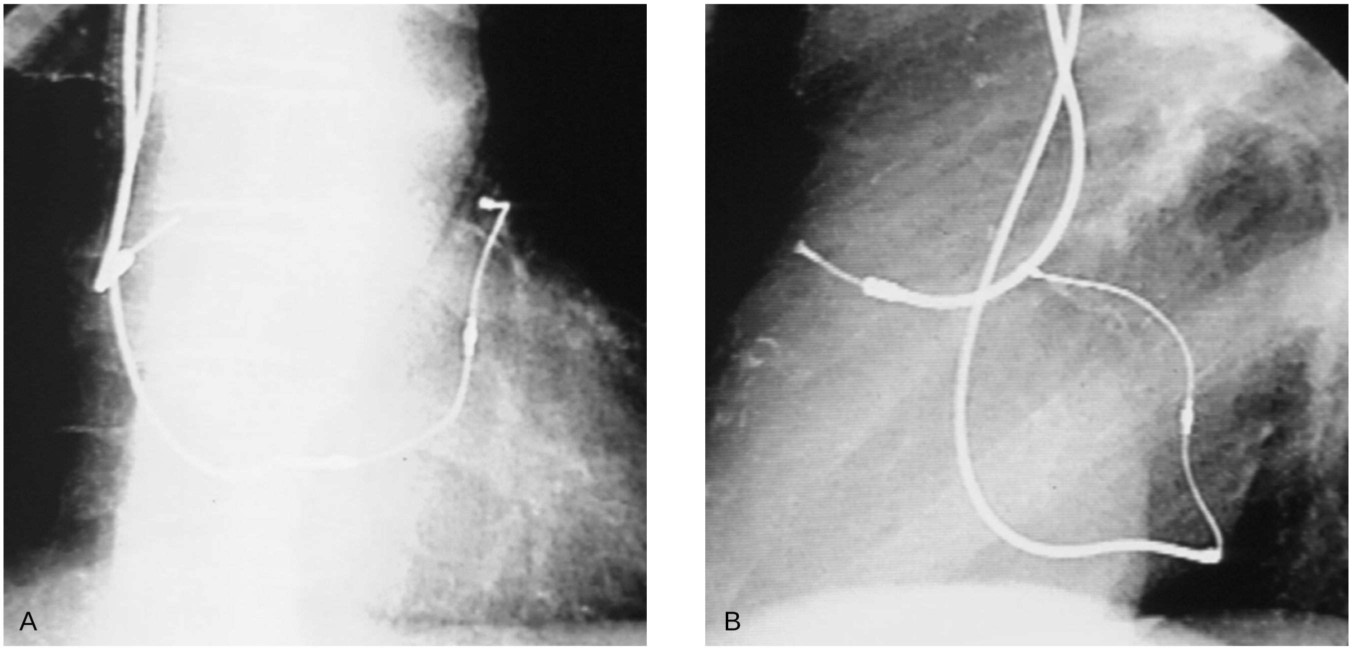

Figure 7. The new Biotronik CS-designed lead: A) PA view. B) Lateral view (LAO 90°). Two BP leads connected with standard DDD pacemaker for permanent BiA pacing. The new designed CS lead is implanted in the CS. Two rings of this lead permit for LA pacing/sensing. An electrically inactive distal tip with longer (than standard) tines play a role in anchoring the strand, resulting in a decreased risk of CS lead dislocation.

lead (Figure 7) experienced excellent results [13]. Our preliminary experiences were very promising, and were similar to those authors who later used this pacing system in small groups (5 and 7 patients) with comparable patients [13,30-34,48,49,50]. Our long-term observations showed that additional surgery was necessary in the post-operative period in 9 out of 47 patients (19%) due to lead dislocation, exit block, or other surgical complications, but eighty percent of patients could be successfully paced for a long-term period.

The reasons for performing additional surgery during the long-term period were related to specific disadvantages of this pacing system: atrial arrhythmias originating from the atrium connected to the ventricular channel of the pacemaker [5 out of 47 patients (11 %)], and late occurrence of AV conduction disturbances. It is important to understand that moderately elevated PTh in the CS does not create real problems, and pacemaker output in the CS-connected channel can be programmed only slightly above the threshold energy. Simultaneous pacing of the RAA with standard output programming provides a safety margin that prevents sudden pacing breaks (and their clinical consequences) [if increasing CS PTh values exceed necessary CS channel output].

The advantages of the BiA (DDD) pacing system are: precise programming output for each atrium (saves energy), separate sensing of both atria in BP configuration (lower V amplitude sensing), the possibility of ring (anode) CS pacing if higher energy is applied in case of tip exit-block, maintenance of atrial pacing in case of dislocation/exit-block of the CS lead, and possibly the separate evaluation of CS pacing/sensing conditions (important for evaluation of new models of CS-designed leads). The main disadvantages of this pacing system are the inability of V pacing if A-V block occurs later, and the inability of resynchronization of premature LA excitations if "standard" mode lead connections are applied.

Conclusions

I. BiA pacing is a very promising mode for suppression of atrial arrhythmias.

II. BiA pacing using a DDD pacemaker is the simplest solution, but the appearance of LA arrhythmias and the risk of AV conduction disturbances remain its main limitations.

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