Epicardial pacing: a single-centre study on 321 leads in 138 patients

Bavo ECTOR[1], Rik WILLEMS[1], Hein HEIDBÜCHEL[1], Marc GEWILLIG[2], Luc MERTENS[2], Bart MEYNS[3], Willem DAENEN[3], Hugo ECTOR[1]

[1]Department of Cardiology; [2]Department of Paediatric Cardiology; [3]Department of Cardiac Surgery, Gasthuisberg University Hospital, Leuven, Belgium.

Objective — This study presents the long-term outcome of 321 epicardial leads in 138 patients.

Methods and results — All leads were Medtronic CapsureEpi model 4965 steroid eluting leads. The 1-, 3-, and 5-year patient survival was 91%, 83% and 77%, respectively. Twenty-seven patients died. In 25/27 deaths a pacing-related death could be excluded. Strangulation of the heart by an abandoned epicardial lead was the cause of death in one child. One other patient died suddenly at the age of 3 years.

Failures occurred in 57 of 321 epicardial leads (18%). For all 321 leads, the 1-, 3- and 5-year freedom from failure was 91%, 85% and 71%, respectively. The cumulative proportion of patients without any lead defect was 85% after 1 year, 76% after 3 years and 62% after 5 years. The percentage of patients without serious adverse events at 1, 3, and 5 years was 97%, 91%, 85%, respectively.

Lead fracture was the cause of failure in 15 leads of 9 patients. An important increase in pacing threshold occurred in 35 leads of 30 patients. Other failures were: diaphragmatic stimulation, infection, excessive traction and strangulation. Eighteen failures were repaired by 11 surgical interventions in 9 patients. Thirty-nine defects were corrected non-invasively in 31 patients.

Conclusions — The use of steroid-eluting epicardial leads has proven to be an adequate option. In paediatric cardiology, the epicardial approach remains an indispensable tool for achieving a lifelong pacing. (*Acta Cardiol 2006; 61(3): 343-351*)

Keywords: *epicardial pacing – steroid-eluting leads – lead defect – fracture – exit block.*

Introduction

In the pacemaker clinic the first concern is to avoid loss of capture, with lead fracture, dislodgement and high pacing thresholds as the main culprits. In pacing practice, three dilemmas are omnipresent: (i) single-, double- or triple-chamber pacing; (ii) the choice between epicardial and transvenous leads; (iii) unipolar versus bipolar leads. At the time of implantation, freedom of choice and haemodynamic considerations are tempered by technical constraints. In epicardial systems, difficulties may arise in finding a stable and electrically acceptable position. Accurate measurements of pacing threshold, impedance and sensing characteristics are mandatory. For safety reasons a technique of redundant pacing has been proposed previously: the connection of two separate transvenous or epicardial ventricular leads to the atrial and ventricular outlet of a dual-chamber pacemaker[1-3]. Such a system offers the opportunity of switching to the pacing lead with the better lead measurements without any additional intervention.

The objective of the present study was to evaluate the long-term outcome of 321 epicardial leads in 138 patients. Despite the technical feasibility to implant endocardial leads in children, the use of epicardial leads may be a more prudent approach. It may minimize long-term vascular and/or valvular injury. The epicardial approach "preserves" the vein for the next many decades of pacing. Moreover, an epicardial approach is indicated in patients with right-to-left shunts, with chambers that cannot be accessed by the transvenous route and in the presence of a mechanical tricuspid prosthesis[2,4]. Over the years, increasing concern has emerged for assuring more safety by providing an additional lead for ventricular pacing. In our

Address for correspondence: Prof. Hugo Ector, Department of Cardiology, Gasthuisberg University Hospital, Herestraat 49, B-3000 Leuven, Belgium. E-mail: Hugo.Ector@med.kuleuven.ac.be

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department, this has resulted in the introduction of a variety of pacing configurations. Important progress may be expected from the more recently introduced triple-chamber pacemakers, the so-called CRT (cardiac resynchronization therapy) devices.

Patients and methods

Between 23 January 1992 and 22 September 2005, 321 unipolar epicardial pacing leads were implanted in 138 patients: 70 male (176 leads) and 68 female (145 leads) patients. Figure 1 illustrates a remarkable increase in the numbers of patients and leads over the last 5 years. The follow-up of these patients extends to 25 December 2005. This patient group accounts for a total of 205 pacemakers. Nineteen patients had already at least one pacemaker implanted before 23 January 1992.

Atrioventricular block was the indication for pacing in 79% of the patients. Congenital heart disease was present in 46% of all cases (55 patients with and 8 without surgery), valve replacement or repair in 29.7%, no structural heart disease in 6.5%. Table 1 gives details on pacing indications and structural heart disease. Overall, the indication for pacing was a postoperative occurrence in 71/138 (51.4%) patients.

The epicardial leads were implanted through a midline (when possible limited) sternotomy, left lateral thoracotomy or subxiphoid approach. The latter surgical approach favoured fixation of the lead on the anterior and diaphragmatic site of the right ventricle. Implant measurements include: P and R wave sensing, pacing threshold and impedance.

All leads were Medtronic CapsureEpi model 4965 leads. These are unipolar silicone leads with a cathode surface area of 14 mm^2. The tip contains 1 mg dexamethasone. The conductor resistance is 38 ohm for 50 cm. Other characteristics are: IS-1 UNI connector, MP35N nickel alloy conductor, body diameter 4.5 French (1.5 mm), sutured fixation. The lead length was 15 cm in 60 instances, 25 cm in 57, 35 cm in 89 and 50 cm in 111 instances. The importance of avoiding large loops of pacing leads in the pericardial cavity has been considered essential for the prevention of cardiac strangulation in children[5,6]. Therefore, the surgeon always adjusted the lead length to the size of the patient.

During this study period, electrotechnical parameters prevailed over haemodynamic considerations. In

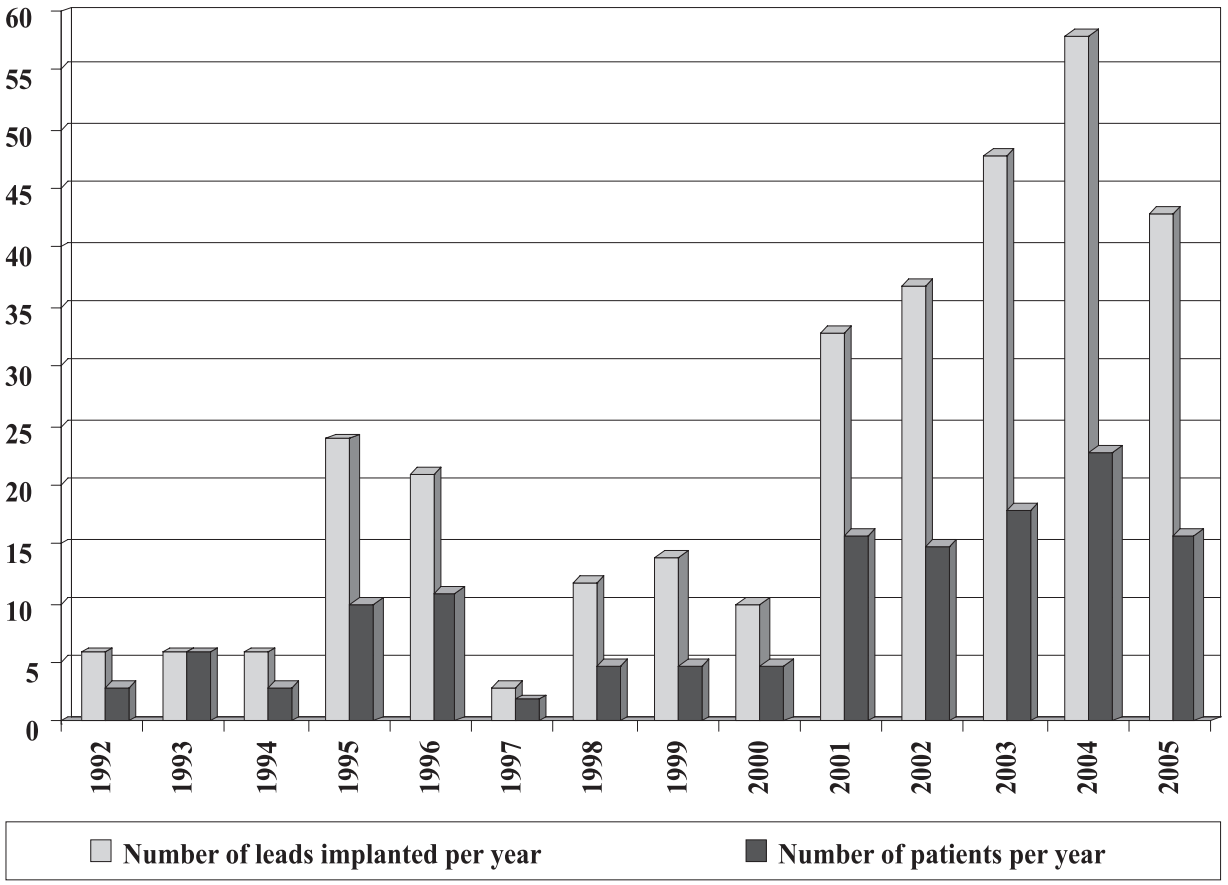

Fig. 1. – Epicardial pacing between 23 January 1992 and 22 September 2005: number of leads per year and number of patients per year.

Table. 1. – *Indication for pacing and structural heart disease.*

In parentheses the number of postoperative cases.

Indication			Associated heart disease		
	Number	%		Number	%
3rd degree AVB	84 (59)	60.9	Congenital heart disease and surgery	55 (47)	39.9
Congenital AVB	20	14.5	Congenital heart disease	8	5.8
2nd degree AVB	5 (2)	3.6	Valve replacement/repair	41 (21)	29.7
Sick sinus	19 (8)	13.8	None	9	6.5
Slow atrial fibrillation	2 (2)	1.4	Infection transvenous system endocarditis	11(3)	7.9
Tachy-brady syndrome	3	2.2	Heart failure	4	2.9
His ablation	2	1.4	Myocarditis	1	0.07
CRT pacing	2	1.4	CABG	2	1.4
LV assist	1	0.7	Maternal lupus	7	5.1

Abbreviations: H = heart; AVB = atrioventricular block; LV assist = left ventricular assist device; CABG = coronary bypass surgery.

Table. 2. – *Site of lead and pacing configuration.*

Site of lead and pacing configuration	Atrial or ventricular lead position									Number of leads	First intervention Number of patients	Second intervention Number of patients	Third intervention Number of patients
	VENTRICULAR	ATRIAL OUTLET PM TO ATRIUM	LV	RV	ATRIAL OUTLET PM TO VENTRICLE	UNCONNECTED SPARE VENTRICULAR LEAD	LV OUTLET TO ATRIUM	UNCONNECTED SPARE ATRIAL LEAD	VENTR OUTLET DDD TO ATRIUM				
VVI + 1 LEAD	14									14	13	1	
VVI+1 LEAD+1 UNCONNECTED SPARE LEAD	12					12				24	12		
DDD+1 ATR+1 VENTR LEAD	14	14								28	13	1	
DDD+1 ATR+1 VENTR+1 SPARE VENTR LEAD	9	9				9				27	9		
DDD+1 ATR+1 VENTR+1 SPARE ATR+1 SPARE VENTR LEAD	4	4				4		4		16	3	1	
DDD+2 VENTR LEADS	66				66					132	62	3	1
DDD+2 VENTR+1 SPARE UNCONNECTED ATR LEAD	1				1			1		3	1		
DDD+2 ATR LEADS+1 SPARE UNCONNECTED VENTR LEAD		2				2			2	6	2		
CRT+1 ATR+2 VENTR LEADS		15	13	16						44	12	3*	
CRT+1 ATR+2 VENTR LEADS+1 SPARE VENTR LEAD		1	1	1		1				4	1		
CRT+1 ATR + 2 RV LEADS		3		6						9	3		
CRT+2 ATR LEADS+1 VENTR LEAD		1		1			1			3	1		
CRT+RV+LV+PLUG ATR OUTLET			3	3						6	3		
CRT+2 RV LEADS+ PLUG ATR OUTLET				2						2	1		
CRT+1EPIC LV+TRANSV ATR+TRANSV RV			1							1	1		
CRT+1EPIC LV+TRANSV ATR+TRANSV RV+SPARE VENTR LEAD			1			1				2	1		
Total number	120	49	19	29	67	29	1	5	2	321	138	9	1
3* Use of a previous lead in one patient													

Abbreviations: Atr = atrial; Ventr = ventricular; VVI = single-chamber ventricular PM; DDD = dual-chamber PM; LV = left ventricle; RV = right ventricle; CRT = triple-chamber PM as used for cardiac resynchronization therapy; Transv = transvenous endocardial lead.

the earlier days, we used to implant a standard single-chamber unipolar pacemaker. An additional spare lead, not connected to the pacemaker, was added to avoid thoracotomy in the case of lead failure. With the smaller size of modern pacemakers, the spare ventricular lead was connected to the second outlet of a dual-chamber pacemaker. We preferred the safety of a second ventricular lead to atrial-based pacing. Since the introduction of triple-chamber CRT pacing, in view of the haemodynamic benefit, when possible a RA, RV and LV position were selected[7]. However, the complexity of congenital heart defects, in several cases, required an alternative pacing configuration. All pacing devices used in this study, had the possibility of being programmed in a rate responsive mode.

There is an important caveat in the use of two ventricular leads with a standard DDD pacemaker: the end of life behaviour of the device. Many devices will automatically switch to a VVI mode. If the VVI outlet is connected to a defective lead, this can result in pacing failure! So, when using the atrial outlet for ventricular pacing, a timely prophylactic pacemaker replacement is mandatory. A similar automatic switch to a defective lead is also possible in some triple chamber CRT devices.

Statistics and follow-up

The study ran from 23 January 1992 until 25 December 2005. We have calculated patient survival in years, between the day of the first lead implant and the last control visit or death. For the lead follow-up, we have made a similar calculation: time interval between implant and defect, patient death or last follow-up visit. Two patients were censored at the time of heart transplantation.

The first follow-up visit was scheduled 2 months after implantation and at subsequent 6- or 8-month intervals. Control measurements included: P and R wave sensing, pacing thresholds and impedance. With the time of generator replacement approaching, the follow-up was intensified to 2- or 4-month periods.

All calculations were done with the Statistical Package for the Social Sciences (SPSS) software for Windows release 11.5.1 (SPSS Inc., Chicago, IL, USA).

Results

Pacing and lead configuration

At the time of their first intervention, 1 epicardial lead was inserted in 14 patients, 2 leads in 92, 3 leads in 28, 4 leads in 4 patients. A second intervention was needed in 9 cases: 1 new lead in 1 patient, 2 new leads

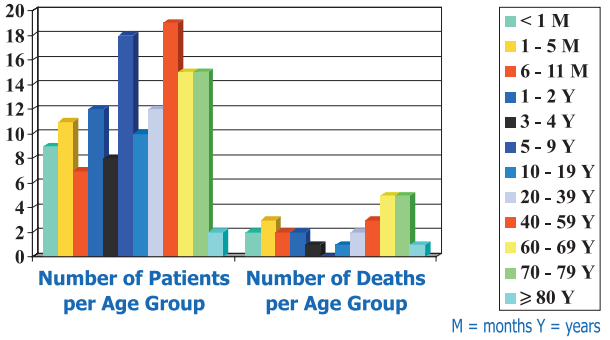

Fig. 2. – Twenty-seven deaths. Number of patients and number of deaths per age group. M = months; Y = years.

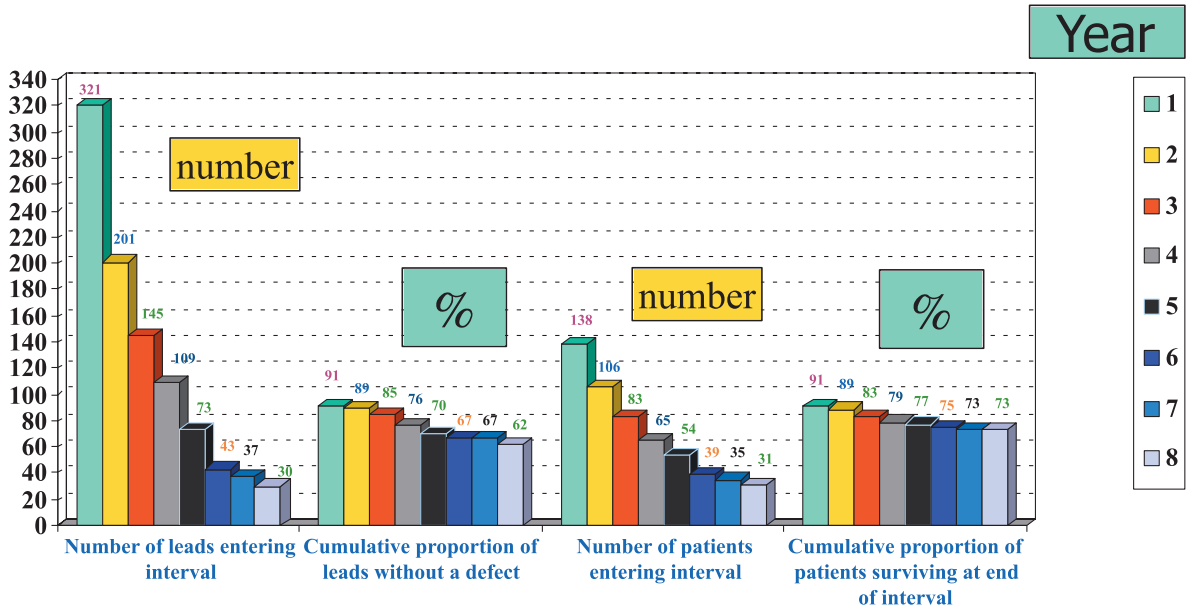

Fig. 3. – Life tables for 321 leads and 138 patients: cumulative proportion of all leads, free from any defect after year 1 to 8; and cumulative proportion of patients surviving after year 1 to 8.

Table. 3. – *Age at time of lead implant and time between lead implant and death.*

	Age at time implant	Time between implant and death	Indication 1st PM	Structural heart disease	Summary
1	7D	3 Y	CONG AVB	CONG NO SURGERY	sudden death
2	22 D	3 M	AVB III	CONG & SURG	postoperative, multi-organ failure
3	3 M	1 M	AVB III	CONG & SURG	postoperative, sepsis
4	3 M	14 D	AVB III	CONG & SURG	postoperative
5	4 M	3 Y	CONG AVB	NONE	intractable pulmonary hypertension
6	10 M	10 M	AVB III	CONG & SURG	intractable pentalogy of Cantrell
7	12 M	15 M	AVB III	CONG & SURG	multi-organ failure after collaps: anaesthesia induction for catheterisation
8	18 M	13 D	AVB III	CONG & SURG	postoperative
9	20 M	16 M	CONG AVB	CONG NO SURGERY	pneumonia, in-hospital death
10	4 Y	2 Y	AVB III	CONG & SURG	sudden death by strangulation
11	14 Y	4 Y	AVB III	VALVE REPL	traffic accident
12	33 Y	3 Y	AVB III	CONG NO SURGERY	sudden death, probable arrhythmia, complex congenital heart disease
13	34 Y	6 Y	AVB III	CONG & SURG	suicide
14	48 Y	10 Y	AVB III	VALVE REPL	abdominal bleeding, prosthetic valve endocarditis
15	57 Y	9 Y	AVB III	VALVE REPL	pneumonia and gastrointestinal bleeding
16	57 Y	5 D	LV ASSIST	HEART FAILURE	CVA after LV assist device
17	61 Y	2 Y	AVB III	VALVE REPL	pneumonia
18	65 Y	16 D	AVB III	VALVE REPL	postoperative, cerebral haemorrhage after valve surgery
19	65 Y	22 D	AVB III	CABG	shock and myocardial infarction after valve surgery
20	70 Y	26 M	AVB III	VALVE REPL	pneumonia, heart failure
21	70 Y	31 M	SICK S	HEART FAILURE	heart failure
22	72 Y	3 M	AVB III	VALVE REPL	multi-organ failure, pneumonia
23	72 Y	7 Y	SICK S	VALVE REPL	heart failure
24	72 Y	2 Y	AVB III	CARCINOMA	carcinoma
25	73 Y	3 M	AVB III	VALVE REPL	multi-organ failure after valve surgery
26	75 Y	3 M	AVB III	VALVE REPL	postoperative, sternitis, sepsis, endocarditis
27	81 Y	8 D	AVB III	NONE	sepsis, endocarditis, infection transvenous lead, multi-organ failure

Abbreviations: D = days; M = months; Y = years; CONG = congenital; SURG = surgery: AVB III = third-degree atrioventricular block; SICK S is sick sinus syndrome; LV assist = left ventricular assist device; REPL = replacement.

in 5 patients, 3 leads in two patients and 4 leads in one patient. A third procedure inserted two new leads in one individual. The exact site of lead fixation was not specified for 79 ventricular and 17 atrial leads. According to our surgeons, the vast majority of these leads were sutured to the right site. For the remaining 225 leads we had a right ventricular position for 155, left ventricular for 30, right atrial for 38 and left atrial position for 2 leads.

Table 2 illustrates all 16 pacing configurations and the different connections between pacemaker and heart. Redundant pacing was provided by 89 ventricular and 3 atrial leads in 92 patients.

Demographic data and patient survival

Epicardial pacing was installed in 138 patients (mean age in years: 28.5, SD 28.7, median 12, interquartile range 54.5, minimum 1 day, maximum 82 years). Seventy male patients had a mean age of 26.3 years (SD 27.7, median 10.2, interquartile range 53.3, minimum 7 days, maximum 79 years). Sixty-eight female patients had a mean age of 30.7 years (SD 29.7, median 15.9, interquartile range 61.8, minimum 1 day, maximum 82 years).

The follow-up duration, from the first epicardial lead implant to death or the last follow-up visit extends to a total of 558 patient years (mean 4, SD 3.7, median 2.6, interquartile range 5.3, minimum 5 days, maximum 13.5 years).

Twenty-seven patients died. Figure 2 gives details on the number of patients and on the number of deaths per age group. Figure 3 is a life table with the cumulative proportion of patients surviving at year 1 to 8. The 1-, 3- and 5-year survival was 91%, 83% and 77%, respectively. The difference in 5-year cumulative survival in men (73%, 16 terminal events) versus women (81%, 11 terminal events) was not significant ($p = 0.19$).

All 27 death causes were documented (table 3). In 25/27 deaths a pacing-related death could be excluded. Strangulation of the heart by an old, abandoned epicardial lead, implanted in June 1990, was the cause of death in one 6-year old boy (table 3, case 10). This case has been reported in detail[5]. One boy died suddenly at the age of 3 years (table 3, case 1). A previous PM control did not reveal any problem.

Lead performance and failure

Between implant date and last control visit, lead failure or death, the duration of follow-up in lead years was: total 817, mean 2.54, SD 2.8, median 1.75, interquartile range 3.6, minimum 1 day, maximum 12.6 years.

Failures occurred in 57 of 321 epicardial leads (18%). An additional complication was caused by an old abandoned, fractured epicardial lead. In this patient group we met 58 lead complications in 36 patients. One failure occurred in 24 patients. Five patients experienced 2 defects, 4 patients had 3 malfunctions and 3 patients even dealt with a 4th event (2 lead failures and one death). Thirty-eight failures occurred in 22 male patients, 20 in 14 female patients.

For all 321 leads, the 1-, 3- and 5-year freedom from failure was 91%, 85%, and 71%, respectively. The 5-year lead survival was significantly different between male (66%) and female (75%) patients ($p = 0.03$).

When we exclude 29 unconnected spare ventricular leads and 5 unconnected spare atrial leads from analysis, the 1-, 3-, and 5-year defect-free survival for the other 287 leads is: 89%, 83% and 71%, respectively.

The cumulative proportion of patients without any lead defect was 85% after 1 year, 76% after 3 years and 62% after 5 years. Patients without a serious adverse event at 1, 3, and 5 years amounted to 97%, 91%, 85%, respectively.

Lead fracture was the cause of failure in 15 leads in 9 patients: 13 conductor (7 patients) and 2 connector breaks (2 patients). The pacing threshold increased to more than 2.5 volt at 0.4 msec pulse duration in 35 leads of 30 patients. In 4 of these patients there was apparent exit block: loss of capture because of a high threshold. Inactivation of LV pacing in a CRT device, because of diaphragmatic stimulation, was necessary in one instance. Reasons for lead removal, each in 2 leads in one patient were: infection, excessive traction, imminent strangulation. Strangulation by an older abandoned lead was the cause of death in one patient. Besides this fatal complication, a potentially life-threatening condition arose in 12 other patients: 4 instances of high threshold with exit block (4 patients), 6 conductor fractures in 5 patients, 2 connector breaks in 2 patients, imminent strangulation in 1 patient.

The mean time between lead implant and failure was 29.4 months (SD 32, median 18, interquartile range 45, minimum 1 day, maximum 106 months). Lead failures developed in less than 2 months in 20 cases (of these: 19 within 10 days), between 2 and 12 months in 5; from 1 to 3 years in 9; between 3 and 5 years in 15; after more than 5 years in 8 instances.

Eleven lead failures were observed in redundant, spare, non-functioning leads at the time of an outpatient visit. The defects were detected, after the implantation, on days 2, 4, 11; after 10 months; after 1.5, 2.6, 3, 4, 4.8, 4.9, 8.9 years. These spare lead defects did not present an immediate threat to the patient. Figure 3 shows the cumulative proportion of all leads, free from any defect, for an 8-year period.

Table. 4. – *Details of lead repair for 58 lead defects in 36 patients.*

Lead failure	Patient number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	Total Number of Leads
High threshold	new transvenous lead & epicardial lead abandoned			1*																																		1
	new epicardial lead																		1																			1
	pacing abandoned	1*																																				1
	PM programmed to other outlet													1*													1					1	1			1		5
	defect in spare lead, no action								1	1	1									1			1		1	1				1					1			9
	spontaneous decrease threshold											1					1	1			1			1				2									1		8
	CRT lead inactivated												1																1			1							3
	high threshold atrial lead: PM in VDD																		1																				1
	reprogramming to other output				1		1									1					1*									1					1				6
Fracture	new transvenous lead & epicardial lead abandoned																																		1			1*
	surgical: connection to spare epicardial lead		2																																			2*
	new epicardial lead		2					2											1																				5*
	PM programmed to other outlet																					1																	1*
	defect in spare lead, no action															1																			1				2
	fracture atrial epicardial lead: PM in VVI										1																												1
	PM in VVI & connected to spare atrial lead at PM replacement										1																												1
Connector defect	surgical: repair kit for connector fracture					1									1																								2*
Excessive traction	new epicardial lead												2																										2
Infection	new epicardial lead							2																															2
Diaphragmatic stimulation	reprogramming to other output																															1						1
Strangulation: imminent	new epicardial lead									2																													2*
Strangulation: death	death																																		1			1
Number of lead failures per patient: colours indicate surgical repairs		1	4	1	1	1	1	4	1	3	3	1	3	1	1	2	1	1	3	1	2	1	1	1	1	1	1	2	1	1	1	2	1	1	4	1	2	58
One failure in 24 patients; 2 failures in 5 pts; 3 in 4 pts; 4 events (1 death) in 3																																						
In yellow: * POTENTIALLY LIFE-THREATENING CONDITION IN 12 PATIENTS: high threshold with exit-block: 4; fracture: 5; connector fracture 2; imminent strangulation 1																																						
In red: surgical procedures (SP): 18 failures requiring 11 SP in 9 patients:											4 SP in 4 patients with 1 failure,										3 SP in 3 pts with 2 failures,										2 SP in each of 2 pts with 4 failures				
39 failures were diagnosed and, if necessary, corrected non-invasively in 31 pts: 3 in 1 pt, 2 in 6 pts, 1 in 24 pts																																						
Four patients needed a surgical as well as a non-invasive procedure																																						

Lead repair

Table 4 gives a complete overview of the therapeutic actions for the 58 lead complications in 36 patients. Eighteen failures were corrected by 11 surgical interventions in 9 patients: 4 procedures in 4 patients with 1 failure, 3 interventions in 3 patients with 2 defects, 2 procedures in each of 2 patients with 4 failures. Fourty other events remained: 1 death and 39 defects. Thirtynine defects were diagnosed and, if necessary, corrected non-invasively in 31 patients: 1 failure in 24 patients, 2 failures in 6 patients, 3 failures in 1 patient. Four patients needed a surgical as well as a non-invasive correction. The non-invasive approach included: (i) abandonment of pacing after one lead defect in one patient; (ii) inactivation of a high threshold left ventricular CRT lead: 3 leads in 3 patients; (iii) reprogramming of the pacemaker output: for 10 leads in 9 patients; (iv) a spontaneous decrease in pacing threshold after a previous rise occurred in 8 leads of 7 patients; (v) no action was required for a defect in 11 spare leads of 11 patients; (vi) pacemaker programmed to other outlet: for 6 leads in 6 patients. These six last failures had appeared, after implantation, on days 1 – 5 – 8; after 2.6 and 3 months, and after 3 years.

Discussion

That, in 1992, the exclusive use of steroid eluting leads was a good option, has been confirmed by different reports[8-12]. Before the routine use of steroid leads, the 5-year epicardial lead survival was 40 to 70%[9,10]. Although dual and triple-chamber pacing were gradually introduced, we have adhered to a strategy – as described by Thomson et al.[11] – of keeping pacing simple, particularly in those patients with structurally normal hearts in whom we tried to avoid a sternotomy or thoracotomy for atrial wire placement. This policy is also supported by other considerations. Already in 1994, Ragonese et al.[13] concluded that, in children without ventricular dysfunction, single-chamber rate responsive pacing offers several potential advantages over the more complex dual-chamber atrial tracking pacing mode. The preservation of atrioventricular synchrony could be unnecessary in selected groups of paediatric patients. Rate responsive ventricular pacemakers seem to adequately respond to the physiological needs of daily life. Also the paper by Horenstein and Karpawich[14] supports VVIR pacing as an adequate and cost-effective initial therapy for symptomatic bradycardia due to complete AV block. In the general practice of cardiac pacing, the definite, but restricted, benefits of physiological or atrial-based pacing are well known[15-25].They are best summarized in a Cochrane review[15], identifying 5 parallel and 26 crossover randomized control trials. Pooled data from parallel studies shows a statistically non-significant preference for physiologic pacing for the prevention of stroke, heart failure and mortality, and a statistically significant beneficial effect regarding the prevention of atrial fibrillation. Both parallel and crossover studies favour dual-chamber pacing with regard to pacemaker syndrome. Pooled data from crossover studies shows a statistically significant trend towards dual-chamber pacing being more favourable in terms of exercise capacity. However, in our patient population, these advantages compete with important electrotechnical and surgical considerations. Moreover, the present pacemaker technology offers different programming features for minimizing right ventricular pacing[25].

Our results of lead survival are similar to these of Cohen et al.[8] and Thomson et al.[11]. However, our preference for a redundant lead system seems to be justified by the substantial number of early postoperative lead failures. Even at the time of implantation, redundancy allows an option for the use of the lead with the best electrical characteristics. The possibility of reprogramming from one PM outlet to another, has definitely avoided 6 surgical interventions in 6 patients. These six failures appeared, after implantation, on days 1 – 5 – 8, after 2.6 and 3 months and, after 3 years. Also, in this respect, the occurrence of eleven lead failures in redundant, spare leads is relevant. These spare lead defects did not present an immediate threat to the patient. The failures were detected, after the implantation, on days 2 – 4 – 11, after 10 months, after 1.5 – 2.6 – 3 – 4 – 4.8 – 4.9 – 8.9 years. These data confirm that, for an approach with only one ventricular lead, a substantial number of additional complications would have emerged.

New developments such as triple-chamber CRT pacing will facilitate redundancy in pacing. For small infants, the size of the pacemaker and its connector may remain a limiting factor. In such cases, we feel that a configuration with 2 ventricular leads, connected to the atrial and ventricular outlet of a small DDD pacemaker, is preferable to the classical atrial-based pacing modes. However, this technique uses the pacemaker beyond its specifications. In some circumstances, an automatic switch to an outlet with a defective lead might occur, especially at the end of life of the device.

Conclusions

In paediatric cardiology, the major concern is not only the immediate result of a particular lead/generator[8], but also, and more importantly, how best to achieve a lifetime of pacing. A pacing strategy including an epicardial approach in younger, smaller, and anatomically difficult children achieves this[11]. We completely concur with these statements. However, in this patient group, despite the overall acceptable results,

epicardial pacing appeared to present its own rare but important complications: the risk of strangulation and excessive lead traction. Regular screening and timely lead replacement can prevent the possible fatal outcome of these complications.

For a complex pathology, such as covered by this study, randomized trials are of restricted help in daily practice. Observational studies remain indispensable, when urgent and difficult clinical decisions are needed for the individual infant, child, adult or elderly patient[26,27].

This paper is a legacy of the experience, generated by a team, working together since 1970.

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