A Long Term Follow-up of Patients with a Permanent Pacemaker: Necessity of Specific Programmer

Ioannis A. Chiladakis, Georgios Agelopoulos, Nikolaos Patsouras, Athanassios Paschalis, Antonis S. Manolis

Regional University General Hospital of Patras, Cardiology Division, Rio, Patras

Key words:
Follow-up, pacemakers.

Introduction: The goal of pacemaker follow-up is not only to predict the end-of-life (EOL) of the pulse generator but also to detect malfunctions and optimize pacing system performance and longevity. In this prospective study we evaluated the effectiveness of pacemaker follow-up with the use of magnet rate measured by the mini-clinic compared with a complete set of tests using pacemaker programmers, in the absence of a transtelephonic monitoring.

Methods: Of a total of 135 patients who had their first visit to our outpatient pacemaker clinic in the last two years, we prospectively selected 37 patients who had their first follow-up examination since implantation (n = 27, mean time 4.5 ± 2.7 years) or had been previously evaluated by mini-clinic alone (n = 10). We analyzed the possible pacemaker dysfunction-related symptoms, the device malfunctions, and the necessity for specific parameter corrections.

Results: Nine patients (24%) were found at battery depletion (ERI/EOL) status, 6 of them (13.5%) were pacemaker-dependent, and 2 patients (5.5%) asymptomatic pacemaker-dependent. Symptoms related to pacemaker dysfunction were noticed in 13 patients (36%). Twelve of 13 losses of capture and sensing (92%) were corrected by reprogramming. In 3 patients the VDD pacemaker had to be reverted to VVI because of atrial fibrillation. Reprogramming to correct various problems was finally required in all patients (100%). Mini-clinic patients had their first complete interrogation via a programmer 7.4 ± 3.7 years after implantation. Five of them (50%) had intermittent capture problems or were found at ERI/EOL status.

Conclusions: Our findings indicate that programmer availability is vital for adequate pacemaker follow-up and should constitute an integral part of a pacemaker clinic. Mini-clinic measurements alone do not maintain patient safety and well-being.

Manuscript received:
February 13, 2001;
Accepted:
December 11, 2001

Correspondence:
Ioannis Chiladakis

6, Tertseti st.
264 42 Patras
e-mail:
ichi@otenet.gr

Undoubtedly, the rapid technological evolution in the field of permanent pacemakers resulted both in increased reliability and functionality of the devices but also in increased obligations of the medical staff with regard to the improvement of the level of know-how and familiarization with the technical characteristics of pacemaker systems. Responsibility, clinical experience, method and specialized knowledge constitute the parameters on which the rational use and exploitation of the possibilities of the implanted device are based. Such parameters constitute the necessary prerequisites for a safe and optimal long-term follow-up of patients carrying a permanent pacemaker.

However, particularly with regard to the control and programming of the permanent pacemaker, we must all admit, implant specialists, non invasive and private cardiologists, that sometimes the medical services provided do not pay tribute to the therapeutic, scientific and technical achievements. Although there

are specific guidelines of international Cardiology Societies and many international and Greek references and suggestions in literature[1-7], daily practice is different. This article presents the experience of our Cardiology Division of the University Hospital in an effort to assess the provision of correct follow-up for patients with a permanent pacemaker. We also assess the reliability of the simple pacemaker follow-up with the use of magnet rate alone and/or with mini-clinic, compared to the advantages of a systematic and complete telemetry programmer follow-up, bringing to light a "tacit" commonly accepted experience of a large Health System Region and possibly of the Greek reality. To date there is no similar systematic and detailed study in literature addressing the above issues. This paper has as objective not to pass judgment but to assess the approach to patients with permanent pacemakers, through time, aiming at drawing useful conclusions that will contribute to the improvement of such approach.

Material and methods

The population of the present prospective study consisted of 37 out of 135 consecutive patients (27%) who first visited the hospital's outpatient pacemakers clinic, for a pacemaker follow-up in the last two years, from January 1999 to January 2001. Our clinic is equipped with special programmers that are used for regular check-up of all pacemaker models, but does not provide for transtelephone monitoring facilities. In this clinic, according to international guidelines[1-7], pacemaker monitoring includes initial monitoring of the pacemaker 6-8 weeks following implantation and then follow-up visits twice a year for dual chamber systems and once a year for single chamber systems.

A selection criterion for the 37 patients (mean age 78 ± 10 years, age range: 41-92 years old) was the first patient visit to a specialized pacemaker clinic, in conjunction with the lack of previous monitoring of the pacemaker using a special programmer, or in conjunction with a past simple monitoring using magnet alone and/or mini-clinic. This was verified both from the patient's and/or his/her testimony, as well as from the absence of a pacemaker card and/or its non filling-in, or its filling-in with data only from the magnet/mini-clinic follow-up. The questionnaire also included information regarding any examination of the patient by cardiologists following the pacemaker implantation and the information of the patient and/or his/her testimony on the results of the pacemaker follow-up.

Following the taking of a complete history and clinical examination, we proceeded to the examination of the implantation site of the pacemaker, electrocardiogram and magnet and mini-clinic examination of the pacemaker (mini-clinic device: Instromedix, Beaverton, OE, USA), with which we evaluated the pacemaker capture and the battery's life. With the mini-clinic device, apart from the pacemaker magnetic frequency, we also evaluated the duration of the pacing stimulus.

The next step involved telemetric monitoring of the pacemaker with the manufacturer's special programmer, that included precise determination of threshold values for pacing and sensing, atrioventricular delay, lead impedance as well as other parameters aimed at solving problems possibly related to the pacemaker's function.

The reprogramming that was performed indicated the significance of a detailed telemetric programmer monitoring, compared to previous simple magnet / mini-clinic follow-up. Chest X-rays, anteroposterior and lateral view, were performed, when deemed necessary, to verify the correct position of the electrodes and their integrity.

Only symptoms that were attributed to pacemaker malfunction and were improved following its restitution, are reported. In patients presenting exit block, other causative factors have been excluded such as metabolic and electrolyte disorders, myocardial infarction or drug interactions.

Results are presented as mean value ± standard deviation on a percent basis.

Results

Patients' demographics and clinical characteristics are presented in table 1 (37 patients, 24 men and 13 women). The material consisted of 18 single chamber pacemakers (49%), of which 7 (39%) were rate responsive and 19 dual chamber pacemakers (51%), of which 4 (21%) had the ability of rate adjustment. In 17 out of 37 patients (46%), the pacemaker had been implanted/replaced in another hospital and in 9 patients (24) in total in an Athens hospital. 27 patients (73%) had not been subject to any follow-up from the day of pacemaker implantation, while 10 patients (27%) reported that their pacemaker had been previously followed-up with magnet/mini-clinic. Total time that elapsed until the

Table 1. Pacemaker follow-up results: Demographic and clinical characteristics

	Total N=37	No F-U N=27	MC (F-U with MC) N=10
Age (yrs)	78±10	78±11	79±7
Male	22 (59%)	15 (56%)	7 (70%)
Female	14 (38%)	12 (44%)	2 (20%)
Implantation in other Hospital	17 (46%)	12 (44%)	5 (50%)
Symptoms	13 (35%)	10 (37%)	3 (30%)
syncope	2 (5%)	1 (4%)	1(10%)
dizziness	4 (11%)	3 (11%)	1 (10%)
dyspnea	6 (16%)	5 (19%)	1 (10%)
weakness	5 (14%)	5 (19%)	0
CHF	2 (5%)	2 (7%)	0
PS	1 (3%)	1 (4%)	0

CHF = cardiac heart failure, F-U = follow-up, MC = mini-clinic, PS = pacemaker syndrom

first complete follow-up of the 37 patients was 5.2 ± 3.1 years (range: 1.1-13 years).

The overall problems of pacemaker malfunction and reprogramming of certain parameters are presented in table 2. Thirteen patients (35%) presented symptoms attributed to pacemaker malfunction. Four patients (11%) presented syncopal episodes and dizziness due to permanent or transient loss of ventricular pacing. Three patients (8%) complained of dyspnea and heart failure symptoms with accompanying pacemaker frequency of 120-130 pulses/minute. Among them, one had pacemaker re-entry

Table 2. Pacemaker follow-up: Pacemaker malfunction and reprogramming.

	Total N=37	No F-U N=27	MC (F-U with MC) N=10
Pacemakers			
follow-up (yrs)	5,2±3,1	4,5±2,7	7,4±3,7
first implantation	33 (89%)	26 (96%)	7 (70%)
replacement	4 (11%)	1 (4%)	3 (30%)
single-chamber	18 (49%)	14 (52%)	4 (40%)
dual-chamber	19 (51%)	13 (48%)	6 (60%)
V-Exit block	4 (11%)	2 (7%)	2 (20%)
A-Exit block	1 (4%)	0	1 (10%)
EOL	3 (8%)	2 (7%)	1 (10%)
ERI	6 (16%)	4 (15%)	2 (20%)
PMT	1 (3%)	1 (4%)	0
reprogrammig			
V-pacing	28 (76%)	25 (93%)	3 (30%)
A-pacing	2 (5%)	2 (7%)	0
V-sensing	2 (5%)	2 (7%)	0
A-sensing	2 (5%)	2 (7%)	0
AVD	3 (8%)	2 (8%)	1 (10%)
VDD → VVI	3 (8%)	3 (11%)	0
VVIR → VDD	1 (3%)	1 (4%)	0

A = atrial, AVD = atrioventricular delay, EOL = end-of-life, ERI = elective replacement time, F-U = follow-up, MC = mini-clinic, PMT = pacemaker-mediated tachycardia, V = ventricular

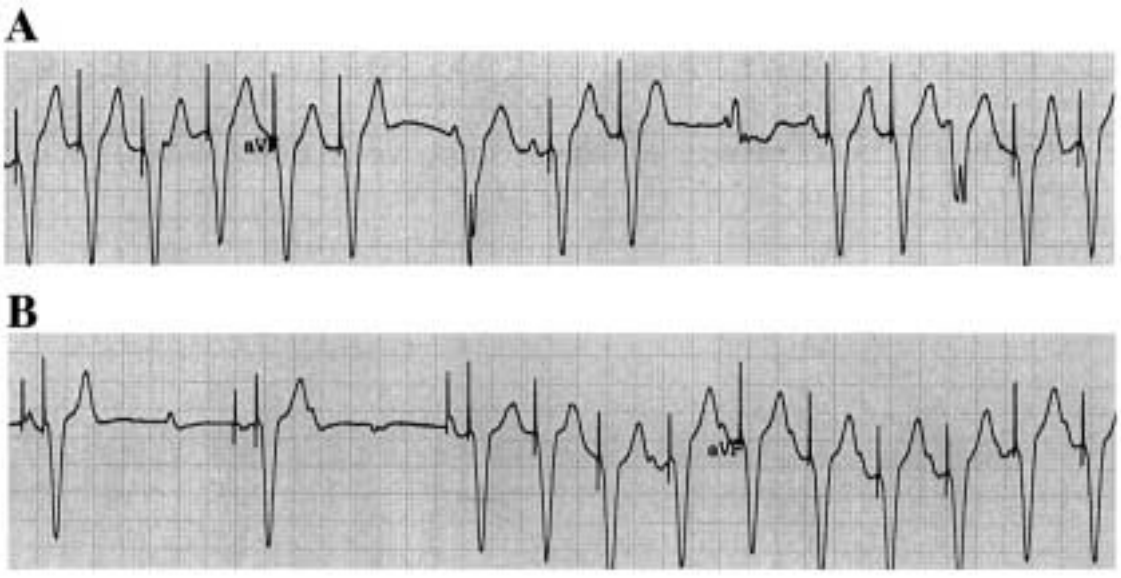

Figure 1. Self-terminating episodes of pacemaker mediated tachycardia (A) in a symptomatic patient with a DDD pacemaker, without any follow-up evaluation 5 years after implantation. In the same patient, intermittent failure of atrial sensing and capture, and initiation of the pacemaker mediated tachycardia at a rate of 130 bpm (B).

tachycardia (Figure 1), whereas in two other patients with a VDD pacemaker, maximum pacemaker frequency was assessed due to transition to atrial fibrillation.

Among 9 (24%) patients as a whole who came to the clinic presenting almost complete battery depletion (ERI-elective replacement time / EOL-end of life), 6 were pacemaker-dependent (16%), 2 were asymptomatic pacemaker-dependent (5.5%) and in 5 (13.5%) patients there was no ability of telemetric communication. In 3 patients with complete atrioventricular block and ERI/EOL, the pacemaker's function had turned into VOO, leading to loss of ventricular sensing and reduction of pacing rate. Two patients with single chamber rate responsive pacemakers had lost the ability of rate adjustment due to ERI stage. In all patients (100%) a modification of the parameters and/or of the pacemaker's function was needed. The output potential was reduced in 28 patients (76%) due to low pacing threshold and was increased in one patient (3%) due to high threshold with a transient loss of pacing. Two patients (5%) with VDD pacemakers regained atrioventricular synchrony following increase of atrial sensing, while in three other patients (8%) the VDD pacemaker turned to VVI due to the development of atrial fibrillation. In a symptomatic patient with complete atrioventricular block, the VVDR pacemaker functioned as VVI. In another patient with DDD pacemaker and lack of atrial capture, chest X-rays revealed dislodgment of the atrial electrode at the output site of the right ventricle.

Patients without any previous follow-up

Twenty-seven patients underwent their first follow-up of their pacemaker 4.5 ± 2.7 years (range: 1.1-10.5 years) following implantation/replacement. Among these 27 patients, 12 (44%) had no pacemaker card. In total, 6 patients (22%) were found at battery depletion status. Two pacemaker-dependent patients with complete atrioventricular block, came at end of life status (EOL) and 4 others, among which two pacemaker-dependent, were in a status of elective replacement (ERI).

In total, ten patients (37%) presented symptoms that were due to pacemaker malfunction. In 7 of them (70%) the symptoms disappeared following appropriate re-programming (n=5) or battery replacement (n=2).

Patients with previous mini-clinic follow-up

Ten patients underwent their first follow-up of their pacemaker 7.4 ± 3.7 years (range: 1.6-13 years) after its implantation / replacement. They all reported that the pacemaker was monitored at regular in-

tervals by the doctor in charge and that they were aware of the correct function of their device. In 2 patients (20%) there was no data on the pacemaker card, while in the remainder only the magnetic rate had been registered from 1.4 ± 0.5 check-ups, in total. Three patients (30%), among whom two were pacemaker-dependent, came at a battery depletion status, one in EOL and two in ERI, without having received any warning and without having been any regular check-ups planned by the doctor in charge after the last examination.

Overall, three patients (30%) presented symptoms that were due to the transient lack of pacing capture and these disappeared following reprogramming or battery replacement.

Discussion

The findings of the present study render necessary the adoption of international scientific guidelines for pacemaker follow-up[1-4]. We should first note that our Health Services Region disposes of two pacemaker centers that cover a population of approximately 1,200,000 inhabitants, and that the total number of operations, new implantations and replacements that are carried out in both centers is approximately 225 per year. The specialized pacemaker clinic of our Hospital provides a regular service of systematic follow-up of implanted devices and is fully equipped with all programmers of several manufacturers.

The first important objective observation of the study conducted is that only a small percentage of patients with permanent pacemakers are subject to complete and regular follow-up, while half of this study's patients did not even have a pacemaker card and neither they, nor their family, seemed to realize its usefulness. Thus, it becomes obvious that what is of utmost importance is the substantial issue of communication, understanding and information of the patients and of their families. They need to realize the necessity of an accurate and precise control, particularly when there are no intense complaints. This is not only true for our own hospital, since almost half of the implantations were conducted in other hospitals and more specifically 9 of them (24%) were conducted in Athens hospitals.

During the study, we found that 27 out of 37 patients (73%) had not been subject to any follow-up for an average period of 3.7 years after pacemaker implantation. We must mainly consider the course of the two asymptomatic but pacemaker-dependent patients, who came at ERI/EOL status by chance. We should also insist on the high percentage of patients (35%) who presented clinical symptomatology that was due to a potentially preventable pacemaker dysfunction and on the fact that 76% of such symptoms disappeared following appropriate reprogramming or replacement of the battery, as well as on the total number of cases where reprogramming of the settings was effected, where feasible (Tables 1, 2). It should also be pointed out that 12 out of 13 (92%) cases of pacemaker dysfunction that occurred were corrected with telemetric monitoring and that chest X-rays were helpful in diagnosis only in one case.

Similar findings resulted following the monitoring of 10 patients who reported that they were under the impression that they were followed up correctly with magnet mini-clinic. Even without a special programmer, the Recommended Replacement Time (RRT) can easily be determined with the use of a magnet/mini-clinic. The RRT is defined as a reduction of the magnetic rate and is an intermediate safety stage, where more regular follow-ups are imposed every one or three months, until the ERI indication of replacement time. Unfortunately, however, we came to the conclusion that although patients were assured of the proper function of their pacemaker, five of them (50%) presented dysfunctions or were seen at the end of battery's life status. Thus, pacemaker monitoring using magnet /mini-clinic, through time, is acceptable when it is conducted with accuracy and method, after the nominal factory values of the battery are set to double threshold with a programmer after at least six months, when the thresholds have been stabilized, and when this monitoring is accompanied by the diagnostic skills of the physician, thus allowing for its optimal function and the successful solution of eventual problems. Under these conditions, consecutive and regular follow-ups with mini-clinic have been proven sufficient in the relatively stable period of the first five years, particularly with regard to single chamber systems[8].

Finally, apart from the obvious usefulness of pacemaker follow-up with a special programmer, as is suggested from the above, we should also underline the extension of the battery life, that is achieved with the reduction of output after the first six months necessary for the stabilization of the threshold, the prevention of disturbance of the

patient due to an early replacement surgery as well as the potential economic benefit[9,10]. All patients of our study underwent reprogramming of the pacing threshold, since all the devices were left with nominal settings following their implantation. A recent study showed that with an appropriate modification of the nominal values, the battery life is prolonged by 64%, that is from 6.5 ±1.5 to 11.1 ±2.7 years[10].

In conclusion, the superficial and rudimentary monitoring of the pacemaker with magnet /miniclinic is not only insufficient but also risky. Correct organization of the pacemaker clinics, active commitment of the physician, continuous information, specialization and possibly supervised assessment of the work produced, constitute the necessary prerequisites for the provision of a safe, high quality service and the exploitation of technological advances.

References

1. Bernstein AD, Irwin ME, Parsonnet V, et al: Report of the NASPE Policy Conference on antibradycardia pacemaker follow-up: effectiveness, needs, and resources. North American Society of Pacing and Electrophysiology. PACE 1994; 17: 1714-1729.
2. Sutton R: Guidelines for pacemaker follow-up. Report of a British Pacing and Electrophysiology Group (BPEG) policy conference on pacemaker follow up. Heart 1996; 76: 458-460.
3. Fraser JD, Gillis AM, Irwin ME et al, for the Canadian working group on cardiac pacing. Guidelines for pacemaker follow-up in Canada: a consensus statement of the Canadian working group on cardiac pacing. Can J Cardiol 1999; 16: 355-363.
4. Vallario LE, Leman RB, Gillette PC, Kratz JM: Pacemaker follow-up and adequacy of Medicare guidelines. Am Heart J 1988; 116: 11-15.
5. Gialafos I: Pacemaker Programming. Cardiology issues 1991; 181-195.
6. Simantirakis EN: The role of pacemaker programming follow-up. Hellenic Cardiology Journal 1995; Appendix A 36: 136-138.
7. Orfanidis ZN: Pacemaker programming and follow-up. Hellenic Cardiology Journal 1997; Appendix A, 38: 44-51.
8. Grendahl H: Pacemaker follow-up with prolonged intervals in the stable period 1 to 5 years postimplant. PACE 1996; 19: 1219-1224.
9. Gillis AM: The impact of pulse generator longenity on the long-term costs of cardiac pacing. PACE 1996; 19: 1459-1468.
10. Crossley GH, Gayle DD, Simmons TW, et al: Reprogramming pacemakers enhances longenity and is cost-effective. Circulation 1996; 94: Suppl II: 245-247.