Pulse amplitude adjustment provides immediate pacemaker longevity gain

Nenad Zlatanovic, Sasko Kedev, Nikola Gjorgov, Branislav Miletic, Antonio Georgiev, Dejan Kovacevic, Ivan Trajkov, Mitko Kaev, Vladimir Borozanov, Vladimir Boskov

Institute for Heart Diseases, University Clinical Center, Skopje, Republic of Macedonia

ABSTRACT

Objective: Adjusting pacemaker pulse amplitude influences the longevity of the pacemaker. Our aim was to establish the initial longevity gain.

Methods: Forty randomly selected patients with implanted pacemakers were analyzed. Mean age was 65.58±13.7 years. All pacemakers were working on factory settings of pulse amplitude 3.5V and pulse width of 0.4 ms for average of 3 years before the adjustment. Initial mean longevity was projected to 68.61±18.86 months, mean battery voltage 2.78V, and mean battery current 14.21±2.61 µA.

Results: Pulse amplitude threshold test was performed and average value of 0.632±0.22V was obtained. Pulse amplitude was programmed to 2.5V and pulse width was left unchanged. New readings of battery data were obtained. Battery voltage did not show immediate changes, and battery current decreased to 11.53±1.98 µA . New average longevity was projected to 81.03±19.82 months, which presents a 12.42 months of initial longevity gain with statistical significance at 95% confidence interval (p=0.003). Positive correlation was found between the new pulse amplitude and new values of battery current (p<0.01).

Conclusion: Pulse amplitude decrease of only 1V provides significant initial longevity gain of more than a year. If found correlations would have any impact on further longevity gains over longer period of time is yet to be established. *(Anadolu Kardiyol Derg 2007: 7 Suppl 1; 216-8)*

Key words: pacemakers, longevity, pulse amplitude, pulse width, pacing threshold

Introduction

Cardiac pacing is still the unsurpassed method of treatment for patients with bradycardia of various origins. Since first pacemakers were implanted, one of the few main imperatives besides its size and capabilities was their longevity. Regardless of the fact that the generator change is routine, quick and somewhere even an outpatients procedure, its still a an invasive procedure and most of the patients would gladly like to prolonged it as much as possible, since they can not avoid it. Therefore prolongation of the pacemaker longevity has been considered highly desirable and cost-effective because it would postpone a second surgical intervention, decreasing the expense for new generators units (1-3).

Pacemaker longevity is usually defined as the interval between pacemaker implantation and detection of its end of service (3-5). Main parameters, which influence generators longevity are pulse amplitude, pulse width, working mode and rates programmed, lead impedance and static energy drain (3). Adjustments of all of these parameters can influence pacemaker longevity, but adjusting the pulse amplitude and pulse width has the most impressive impact on pacemaker longevity. Adjustment of the pulse amplitude is feasible if threshold values and lead impedance are acceptable, and must provide at least 100% safety margin.

Unfortunately, despite the known results of the adjustment of those parameters, it is well known that even in the US, only 43% of patients comply with the pacemaker follow-ups (8). In Germany in 1991 52.1% of pacemakers interrogated postmortem were in factory mode (9).

Despite ever more used Autocapture system for pulse amplitude automatic adjustment, we were interested in the results of manual pulse amplitude adjustment. Our study aims to estimate the immediate effect of pulse amplitude on the pacemaker longevity.

Methods

Patients

Forty patients were evaluated during 2006. They were all implanted and follow-ups done at the Pacemaker Center at the Institute for Heart Diseases, Skopje, Republic of Macedonia. Mean age was 65.58±13.7 years. Average year of implantation was 2003, and most of the devices were functioning in the factory settings at the time of the study (Pulse amplitude 3.5V and Pulse width 0.4ms). Of 40 pacemakers 15 were programmed to VVIR, 11 DDDR, 7 DDD, and 7 VDDR modes.

Pacemakers

Study included Sigma Series (Medtronic Inc) pacemakers: 15 were in VVIR mode, 11 were in DDDR mode, 7 were in DDD mode, and 7 in VDDR mode. Steroid eluting ventricular and atrial tines electrodes were used in all cases.

Study protocol

All patients underwent history taking, physical examination,

Address for Correspondence: Dr. Nenad Zlatanovic, Institute for Heart Diseases University Clinical Center, Vodnjanska bb, 1000 Skopje, Republic of Macedonia
Phone: +38 923147532 Fax: +38 923164134 E-mail: zlic2009@ukim.edu.mk

and electrocardiogram (ECG) recordings. Pacemaker interrogation was performed using Medtronic 9190C programmer. Values of the estimated initial and longevity estimation following the pulse amplitude adjustment provided by the programmer were assessed in our study. Pulse amplitude and pulse width threshold tests using Automatic threshold test were performed to all patients.

The following parameters were assessed at initial and second interrogation: longevity (mean, maximum and minimum), battery voltage, battery impedance, battery current, pulse amplitude, pulse width, threshold values.

Statistical analysis

Statistical analyses including t-test, comparison of means of two samples and Pearson correlation test was performed using Statgraphics Plus (Statistical Graphics Corp).

Results

Initial interrogation results are shown in Table 1 and Table 2. Average threshold test value obtained was 0.632±0.22V, which allowed decreasing the pulse amplitude to 2.5V, providing safety margin of 4:1. Pulse width was unchanged.

New interrogation of devices was performed considering the new pulse amplitude settings and following results were obtained (Table 3 and Table 4). Initial longevity gain after the pulse amplitude adjustment was 12.42 months.

Relationship of new pulse amplitude with pacemaker longevity and battery current is represented in Table 5. Pearson correlation shows statistically significant correlation between new pulse amplitude value and new battery current (p=0.003). No significant correlation however was found among other assessed parameters.

Table 1. Pacemaker`s initial interrogation results

Parameters	Initial interrogation results
Pulse amplitude, V	3.5
Pulse width, ms	0.4
Battery voltage, V	2.78±0.11
Battery impedance, ohm	521
Battery current, µA	14.21±2.61
Data are presented as Median and Mean±SD values	

Table 2. Pacemaker`s initial longevity

Parameters	Mean	Maximal	Minimal
Initial estimated longevity, months	68.61±18.86	83.32±21.6	54.13±16.5

Table 3. Pacemaker`s second interrogation results

Parameters	Second interrogation
Pulse amplitude, V	2.5
Pulse width, ms	0.4
Battery voltage, V	2.78
Battery impedance, ohm	523
Battery current, µA	11.53±1.98
Data are presented as Median and Mean±SD values	

Discussion

Prolonging pacemaker longevity is still a challenge despite tremendous advancement of the contemporary pacing. Sharing the same power source, generating impulses and functioning of the pacemaker "mind" have even further limited pacemaker longevity, especially by introducing new pacemaker diagnostics and functions.

Increasing pacemaker longevity would have several impacts on patients, society, and economy (3). More or less, every patients question before or after the implantation and most certainly at every follow up is how long will his pacemaker last. And while most of them arrive at the clinic with a sense of anxiety, expecting words of near end of their pacemaker, they all feel very relieved when they hear that their pacemaker have substantial time left. For this reason a number of patients do not show at the follow-ups, and unfortunately some of the have their pacemaker end of service suddenly sometimes very traumatized (3). This is why we always encourage our patients with newly implanted pacemakers to comply with the follow-ups regularly.

The economical impact of this strategy cannot be ignored either. Crossley et al. (2) while studying the efficacy of the cost-effectiveness of reprogramming have calculated the mean cost of this benefit of 110$ per patient, for 4.25 years of increased longevity. It was estimated by Gills that by reprogramming pulse amplitude to 3.5V opposed to factory setting of 5.0V estimated savings by patients are 2139-4584 depending of the pacemaker type with total delivery battery capacity being of great importance (11).

Apart from manual amplitude adjustments, Autocapture system provides its automatic adjustment in some pacemaker type. It allows the output to be automatically adjusted based on automatic evaluation of the pacing threshold (12, 13).

We proved that with even a modest decrease of the pulse amplitude, a significant initial increase of its longevity is provided. Although our findings do comply with previously published papers, we thought that addressing the issue one more time would remind all of us the great benefits of this simple procedure. Since we are reporting just the initial pacemaker longevity gain, long-term effects of the pulse adjustment will be subject of further investigation.

Table 4. Pacemaker`s new estimated longevity

Parameters	Mean	Maximal	Minimal
New estimated longevity, months	81.03±19.82	98.24±22.03	64.39±18.4

Table 5. Correlation of new pulse amplitude with pacemaker longevity and battery current

Parameters	95% CI	p
Mean longevity analysis	-21.266 – -3.575	0.003
Maximum longevity analysis	-24.906 – -4.936	0.001
Minimum longevity analysis	-18.177 – -2.34	0.001
Battery current	1.61 – 3.74	0.000001
CI- confidence interval		

Conclusion

We reported that a pulse amplitude decrease of only 1V provides significant initial longevity gain of more than a year, suggesting that this simple procedure of great benefit should be done whenever other parameters like pacing threshold allow it.

References

1. Barold SS, Zipes DG. Cardiac pacemaker and antiarrhythmic devices. In: Braunwald E, editor. Heart Disease. A Textbook of Cardiovascular Medicine 5th edition. Philadelphia: WB Saunders, 1997. p. 705-41.
2. Crossley GH, Gayle DD, Simmons TW, Haisty WK, Bailey JR, Davis-O'Brien K, et al. Reprogramming pacemakers enhances longevity and is cost-effective. Circulation 1996; 94 (9 Suppl): II245-7.
3. Ribeiro AL, Rincon LG, Oliveira BG, Mota CC, Pires MT. Enhancing longevity of pacemakers through reprogramming. Underutilization and cost-effectiveness. Arg Bras Cardiol 2001; 76: 437-44.
4. Underreker DF, Shepard RB, Schmidt CL, Crespi AM, Skarstad PM. Power sources for implantable pacemakers. In: Ellenbogen KA, Kay GN, Wilkoff BL, editors. Clinical Cardiac Pacing. Philadelphia; WB Saunders: 1995. p. 91-111.
5. Stokes KB, Kay GN. Artificial electric cardiac pacing. In: Ellenbogen KA, Kay GN, Wilkoff BL, editors. Clinical Cardiac Pacing. Philadelphia; WB Saunders: 1995. p 1-37.
6. Gregoratos G, Cheitlin MD, Conill A, Epstein AE, Fellows C, Ferguson TB Jr, et al. ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: Executive Summary-a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). Circulation 1998; 97: 1325-35.
7. Bernstein AD, Irwin ME, Parsonnet V, Wilkoff BL, Black WR, Buckingham TA, et al. Report of the NASPE Policy Conference on antibradycardia pacemaker follow-up: effectiveness, needs, and resources. North American Society of Pacing and Electrophysiology. Pacing Clin Electrophysiol 1994; 17: 1714-29.
8. Griffin JC, Schuenemeyer TD, Hess KR, Glaeser D, Anderson BJ, Romans E, et al. Pacemaker follow-up: its role in the detection and correction of pacemaker system malfunction. Pacing Clin Electrophysiol 1986; 9: 387-91.
9. Irnich W, Kramer E, Mueller R. The programming of cardiac pacemakers wish and reality. Dtsch Med Wochenschr 1991: 116: 601-5.
10. Barold S, Stokes K, Byrd CL, Venes R. Energy parameters in cardiac pacing should be abandoned. Pacing Clin Electrophysiol 1997; 20: 111-21.
11. Clarke M, Liu B, Schuller H, Binner L, Kennergren C, Guerola M, et al. Automatic adjustment of pacemaker stimulation output correlated with continuously monitored capture thresholds: a multicenter study. European Microny Study Group. Pacing Clin Electrophysiol 1998; 21: 1567-75.