

From Unipolar to Bipolar Leads: Fewer Problems, More Advantages?

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Summary

The ideal pacing lead remains an elusive goal. The controversy about the ideal pacing lead polarity has continued for many years with respect to which system is the superior: unipolar or bipolar. The aim of our study was to compare unipolar and bipolar leads implanted in VVI patients by estimating the incidence of pacing and sensing dysfunction episodes in 24-hour ECG Holter recordings. Retrospective analysis of Holter recordings was performed for two patient groups: Group UP consisted of 130 patients with VVI pacemakers and unipolar leads, implanted in 1993 – 1995, while group BP consisted of 130 patients with VVI pacemakers and bipolar leads implanted in 1998 – 2000. In all these patients, 24-hour Holter monitoring was performed 3 – 24 months after pacemaker implantation in order to evaluate oversensing and undersensing as well as pacing disturbances. In patients with unipolar leads, the most frequently observed disturbances were oversensing events, caused by myopotential detection. Holter monitoring showed pauses of up to 1150 – 2600 ms, which appeared at various times of the day. The second most common disturbances were undersensing episodes, which were noted in six patients. Ineffective pacing was also observed, accompanied by pauses from 1200 ms up to 3800 ms and without hemodynamic consequences. In two patients, pauses were caused by exit block, and in another two patients by lead fracture. A new lead was implanted in all four patients. In the group of patients with bipolar leads, sensing disturbances occurred in only two patients: one experienced oversensing with a pause of 1300 ms, and the other had an episode of undersensing. In patients with a VVI pacemaker, implantation of bipolar leads was associated with a significantly decreased incidence of under- and oversensing compared to implantation of unipolar leads. Progress in endocardial lead technology reduces the risk of loss of capture in VVI patients.

Key Words

Unipolar leads, bipolar leads, Holter monitoring

Introduction

The cardiac pacemaker lead, the "Achilles heel" of pacing hardware, is a relatively fragile cable of insulated conductor wire implanted into the hostile environment of the human body [1]. The ideal pacing lead remains an elusive goal. Important lead characteristics include ease of surgical insertion with safe and reliable fixation in the myocardium and a high level of electrical performance [2]. The pacing lead of the twenty-first century should be safe, thin, and long-lasting, with reliable sensing and low threshold pacing [1]. The question about the ideal pacing lead polarity has continued undebated for many years with respect to which is the superior system: unipolar or bipolar.

The unipolar pacing system is most probably responsible for the advantages and the limitations of this type of cardiac pacing. The design simplicity, relative thinness (due to the presence of only one coil), flexibility, and possibility of a lower pacing threshold are the most important advantages of unipolar leads. Conversely, unipolar systems present several limitations: significantly higher skeletal myopotential oversensing, the possibility of inappropriate far-field source sensing, and cross-talk during dual-chamber pacing (which may sometimes be life-threatening) [3].

Bipolar pacing is less likely to result in extracardiac pacing, and bipolar sensing does not detect myopotentials,

far-field signals, or electromagnetic interferences. Advocates of unipolar leads argue that bipolar leads have a historically higher failure rate than unipolar leads. Although this is true, if the specific failures of Pellethane 80A and 55D (Dow Chemical Company, USA) are removed from the analysis, the failure rate between unipolar and bipolar lead designs does not differ significantly. Another disadvantage of bipolar leads is that there is no possibility of repairing a conductor fracture or insulation break [4].

The Aim of Our Study

The aim of our study was to compare unipolar and bipolar leads implanted in VVI patients by estimating the incidence of pacing and sensing dysfunction episodes using 24-hour ECG Holter monitoring.

Materials and Methods

Study Population

A retrospective analysis of Holter recordings in patients with implanted VVI pacemakers was performed. The analyzed recordings were from two patient groups, divided according to the type of implanted lead (unipolar versus bipolar). Group UP consisted of 130 patients with VVI pacemakers (Neos 02 UP, Leptos, Biotronik, Germany) and unipolar leads (TIR 60-UP, Biotronik) implanted in 1993 – 1995, while group BP consisted of 130 patients with VVI pacemakers (Actros S and Kairos S, Biotronik) using unipolar pacing and bipolar sensing at 2.5 mV sensitivity with bipolar leads (TIR 60-BP, Biotronik) implanted in 1998 – 2000. Endocardial, passive fixation leads were used in both groups. In all these patients, 24-hour Holter monitoring was performed from 3 to 24 months after pacemaker implantation in order to evaluate over- and undersensing as well as pacing disturbances.

Holter Monitoring

We performed 24-hour Holter monitoring using MR 45 recorders (Oxford Instruments, UK). Recordings were analyzed using a Medilog Excel 2 system (Oxford Instruments). Typical CM₅ and CM₂ channels were used for the Holter recording (similar to V₅ and V₂ in standard 12-lead ECG diagnosis). Both automatic and manual analyses were performed using a special pacemaker analysis program. The manual analysis included hourly evaluations of the minimum and maximum heart rate as well as an analysis of the pauses over the

programmed basic pacing rate. Apart from tabular analysis and histograms, all recordings were evaluated in beat-to-beat format. The following episodes were described: failure to pace, failure to sense (over- and undersensing). Failure to pace was described as a lack of effective pacing after a pacemaker spike, while undersensing was described as an inappropriate pacemaker spike and oversensing as too long an interval between paced spikes (longer than the basic pacemaker rate). Recordings with artifacts over 10% were excluded from the study.

Statistical Analysis

For the statistical analysis, a Student's t test, chi-square test, and Fisher exact test were used where appropriate. The results are presented as mean values \pm standard deviation for metric data. A p-value of < 0.05 was considered statistically significant.

Results

In 1993 – 1995 (group UP), the most frequent indication for pacemaker implantation was AV block, while in 1998 – 2000 (group BP) chronic atrial fibrillation (brady-tachy syndrome) with pauses over 3 s constituted the predominant indication. In patients with sick sinus syndrome (SSS), VVI pacemakers were implanted three times more frequently in 1993 – 1995 than in the 1998 – 2000 period. Both groups did not differ statistically according to mean age and the time from implantation to Holter recording. The characteristics of both groups are illustrated in Table 1.

In patients with unipolar leads, the most frequently observed disturbances were oversensing events, as demonstrated by pacemaker inhibition. Holter monitoring showed pauses of up to 1150 – 2600 ms, which appeared at various times of the day. The second most common disturbances were undersensing episodes, which were noted in six patients. Ineffective pacing was also observed, with accompanying pauses from 1200 ms up to 3800 ms and without hemodynamic consequences. In two patients, pauses were caused by exit block, and in another two patients by lead fracture. All these episodes resulted in the implantation of a new lead. In the group of patients with bipolar leads, sensing disturbances occurred in only two patients: one experienced oversensing with a pause of 1300 ms and the other had an episode of undersensing. The results are summarized in Table 2.

| | Gender | Age (years) | Time from implantation (months) | Indication for implantation | | | |
|-----------------|-----------------|-------------|---------------------------------|-----------------------------|----------------|-------------|--------|
| | | | | AV block | Sick sinus, AF | Brady-tachy | Others |
| Group UP | Female 82 (63%) | 68.5 ± 7.3 | 17.5 ± 6.1 | 55% | 20% | 20% | 5% |
| | Male 48 (37%) | | | | | | |
| Group BP | Female 74 (57%) | 70.5 ± 7.3 | 16.8 ± 5.8 | 23% | 7% | 60% | 10% |
| | Male 56 (43%) | | | | | | |
| p-value | | ns | ns | < 0.05 | < 0.05 | < 0.05 | < 0.05 |

Table 1. Clinical characteristics of studied patients. UP = unipolar leads; BP = bipolar leads; AV block = atrioventricular block; AF = atrial fibrillation; ns = no statistical significance.

| | Total | Undersensing | Oversensing | Exit block | All pacemaker dysfunction events |
|-----------------|-------|--------------|-------------|------------|----------------------------------|
| Group UP | 130 | 6 (4.6%) | 18 (13.8%) | 4 (3%) | 28 (21.5%) |
| Group BP | 130 | 1 (0.8%) | 1 (0.8%) | 0 (0%) | 2 (1.5%) |

Table 2. Pacing and sensing disturbances detected in Holter monitoring. UP = unipolar leads; BP = bipolar leads.

Discussion

Holter monitoring is a valuable tool for diagnosing pacing abnormalities in pacemaker patients [5-10]. Twenty-four-hour ECG monitoring allows for the evaluation of sensing and pacing, detection of asymptomatic pacing disturbances, and determination of arrhythmia occurrences over the course of the day and under various conditions of daily life [11-14]. The value of Holter electrocardiography in patients with pacemakers was first suggested by Ivengar et al. in 1971 by documenting pacemaker failure [5]. The report of Mymin et al. from 1973 describing symptomatic myopotential interference in unipolar VVI pacemakers suggested that such disturbances of the pacemaker's function could also be detected by Holter electrocardiography [15]. In 1974, Bleifer reported pacemaker malfunctions (presumably in VVI devices) using Holter recordings in 18% of patients thought to have normal pacemaker function at the time of routine follow-up and recommended that all patients with a newly implanted pacemaker should have Holter recordings before leaving the hospital [16]. Most of the literature regarding Holter electrocardiography in pacemaker patients involves relatively simple single-chamber devices, mostly in the VVI mode.

Our results revealed a significantly lower percentage of VVI pacemaker dysfunction in patients implanted with bipolar leads. The most significant difference between the compared groups concerns the number of

episodes of oversensing (myopotential inhibition): 18 patients in the UP group versus one patient in the BP group. This phenomenon may have an important clinical implication, even leading to life-threatening pauses with subsequent syncopal episodes. The sole incident of pacemaker inhibition observed in a patient with a bipolar lead lasted 1120 ms. It is likely that this event was caused by external electromagnetic interference.

Undersensing was observed six times more frequently in the UP group than in the BP group. This may be surprising, as according to Furman the polarity of an electrode should not influence the R-wave amplitude [18]. The explanation for this phenomenon may be the fact that nowadays the R-wave amplitude is measured during implantation in order to optimize lead sensing. In 1992 – 1994, this procedure was not being performed. The second reason for undersensing disturbances and muscle stimulation in four patients from the UP group was lead insulation failure confirmed during surgical revision.

Loss of capture was observed in four patients in the UP group. In two patients from UP group, entirely ineffective pacing occurred due to lead fractures, which were probably caused by ligature. Additionally, during the 1993 – 1995 period, rubber fixation sleeves were not being used to anchor the lead at the incision site where it enters the vein. In two other patients, the implanta-

tion of a new lead was necessary because of high pacing thresholds of 4.2 V and 5.1 V measured during surgical revision. In pacemakers implanted in 1992 – 1994, there was no possibility to measure the pacing threshold at hospital discharge and during follow-up. Therefore, incidents of increasing pacing thresholds were missed.

When comparing our experience with pacemakers implanted in 1992 – 1994 and 1998 – 2000, significant differences in the number and type of observed pacemaker function disturbances were observed. The progress that has occurred in the technology of implanted leads, such as improved fixation, an increasingly higher percentage of implanted bipolar leads, more modern materials used in the electrode production process, and increasingly careful intra- and post-operative control of pacemaker parameters, has contributed significantly to the decrease of observed pacemakers dysfunction episodes [18-22]. Modern pacemakers, fully programmable with telemetric functions, enable the physician to check for proper functioning after implantation and during follow-up [23]. A change in the implantation technique to "blind subclavian vein puncture" [24-26] increases the risk of "crush syndrome" [27-29]. This phenomenon may have further implications, leading to an increased number of sensing disturbances in the future. It should be emphasized that in our study only a two-year period after implantation was analyzed. Prolongation of time from implantation may lead to an increase in pacemaker disturbances episodes.

Conclusion

- Implantation of bipolar leads results in a significantly decreased number of under- and oversensing episodes in patients with VVI pacemakers compared to unipolar leads.
- Progress in endocardial lead technology reduces the risk of loss of capture in VVI patients.

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