Scientific Research Publishing

World Journal of Cardiovascular Diseases, 2024, 14, 547-556
https://www.scirp.org/journal/wjcd
ISSN Online: 2164-5337
ISSN Print: 2164-5329

# The Peripheral Hospital as Focal Point for Pacemaker Activity: Review of the Last 300 Implantations Carried out at the Haute Correze Hospital Center

**Mazou Temgoua[1,2*], Alain Berenfeld[1], Lionel Blasco[1], Benoit Guy-Moyat[2]**

[1]Cardiology Department, Haute Correze Hospital Center, Ussel, France
[2]Cardiac Arrythmia Unit, Cardiology Department, Dupuytren University Hospital, Limoges, France
Email: *mazoutemgoua@gmail.com

**How to cite this paper:** Temgoua, M., Berenfeld, A., Blasco, L. and Guy-Moyat, B. (2024) The Peripheral Hospital as Focal Point for Pacemaker Activity: Review of the Last 300 Implantations Carried out at the Haute Correze Hospital Center. *World Journal of Cardiovascular Diseases*, **14**, 547-556.
https://doi.org/10.4236/wjcd.2024.149047

**Received:** August 10, 2024
**Accepted:** September 11, 2024
**Published:** September 14, 2024



## Abstract

**Background:** Pacemaker implantation is a very old activity which has revolutionized the cardiology practice throughout the world. This activity is effective at the Haute Correze Hospital Center since more than 20 years. Due to progress in this area, and the increasing request within this center located at the outskirts of town, we set out to evaluate our pacemaker activity in general and more specifically to assess the post-procedural complications in our series patients. **Methodology:** This was a retrospective longitudinal study. Data were recorded for period of 90 months from 27/05/2016 to 19/11/2023. This data collection was possible via a specific register completed by computerized patient data from the Sillage™ software. All files of patients implanted with single or dual chamber pacemakers were included, generator replacements, upgrading procedures and addition of leads were excluded. The sampling was non-probabilistic, consecutive and non-exhaustive. Statistical analysis was carried out using the Excel 2019 spreadsheet and SPSS version 23 software. The quantitative variables were presented as mean ± standard deviation, the qualitative data as proportions. **Results:** A total of 303 first-time pacemaker's implantations were carried out during the study period (rate of 40 per year). The average age in the population was 79.7 ± 9.4 years (44 - 99 years) with a male predominance of 63.7% (n = 193). Atrioventricular block (2nd and 3rd degree) was the main indication for pacemaker implantation in 42.9% of cases (n = 130). Patients were most often implanted with a dual-chamber pacemaker (57.7%, n = 175). The approach was most often cephalic in 72.6% of cases (n = 220), followed by the subclavian access in 27.4% of cases (n = 84). The average fluoroscopy time was 7.9 min ± 2.4 (1 - 43). The average irradiation dose

in gray/cm$^2$ was 12.4 ± 9.3 (0.22 - 117.5). The average length of hospitalization was 7 ± 4 (2 - 26) days. The overall complication rate at one year was 12.9% (n = 39). These complications are distributed as follows: Leads dislodgement in 8.2% (n = 25), hematoma 3.6% (n = 11) all without clinical consequences, pneumothorax 0.7% (n = 2), both cases of pneumothorax did not require specific care, infection (superficial) in 0.3% (n = 1). Leads dislodgement occurred after a median time of 18 days (IQR: 3 - 36). The earliest dislodgement was observed on D0 and the latest on D207. No serious complications were recorded. The average atrial threshold at implantation/first control/last follow-up was 0.7/1.3/0.8 V, respectively. The average ventricular threshold at implantation/first control/last follow-up was 0.5/1.08/0.87 V, respectively. The average atrial detection at implantation/first control/last follow-up was 3.2/2.3/2.05 mv, respectively. The average ventricular detection at implantation/first control/last follow-up was 10.3/11.03/10.8 mv. The average atrial impedance at implantation/first control/last follow-up was 610/457/457 ohms. The average ventricular impedance at implantation/first control/last follow-up was 754/547/563 ohms. **Conclusion:** Pacemaker implantation is safe at the Haute Correze Hospital Center with a relatively low rate of complications, in this case an almost zero major infection and no serious hematoma. The peripheral hospital should remain a focal point of this activity in order to respond more quickly to the needs of the populations.

## Keywords

Peripheral Hospital, Pacemaker, Haute Correze Hospital Center

## 1. Introduction

Pacemaker implantation is a current activity over the world with more than 1000 implantations per million people in France, Italy, and Sweden [1]. Post-procedural complications are associated with high morbi-mortality and healthcare cost [2] [3]. According to the most experience, this prospective randomized trial of 2010 patients, the complication rate during the median of 33.1-month follow-up was 7.5% [4]. The rate of complication was 9.5% in a large population-based cohort study of 5918 Danish patients who underwent cardiac implantable device treatment [5]. Except for these two studies, the overall complications across previous reports ranged between 5% - 6% for any complication and 3% - 4% for major complications after pacemaker implantations [6]-[8]. These complications included, infections (local and systemic), pneumothorax, cardiac perforation, hematoma, lead dislodgement [5]. The predictors of such complications included: patients characteristics (female gender, underweight), implanted in a center with an annual volume less than 750 procedures, dual versus single chamber, upgrading or lead revision, operator with an annual volume less than 50 procedures, or underwent an emergency, out-of-hours procedure [5]. According to the European Heart Rhythm Association (EHRA), pacemaker implantations have increased by

20% over the last 10 years period [2]. The Haute Correze Hospital Center has been practicing this activity for more than 20 years. Due to progress in this area, and the increasing request within this peripheral center, we set out to evaluate our pacemaker activity in general and more specifically to assess the post-procedural complications in short and medium term in our series. The results will be compared with existing literature and particularly the 2021 EHRA consensus of optimal implantation technique [2].

## 2. Methods

### 2.1. Study Design and Setting

This was a retrospective longitudinal study. Data collection was carried out over a period of 90 months from 27/05/2016 to 19/11/2023 in the cardiology department of the Haute Correze Hospital Center (HCHC).

### 2.2. Study Population and Data Sources

Data collection was conducted by a trained paramedical staff, through a specific register. All files of patients implanted with single or dual chamber pacemakers were included, generator replacements, upgrading procedures, revisions and addition of leads were excluded. Follow-up data were found through Sillage™ software.

### 2.3. Implantation Procedure

All implantation was conducted by two principal national certified operators assisted by one nurse and one manipulator. Interventions occurred in the operative room under local anesthesia. The technique follow major steps of 2021 EHRA guidelines on optimal implantation [2]. As a prerequisite active infection was check before implantation, antimicrobial prophylaxis by cephazolin 1 - 2 g within 1 h of incision or Vancomycine 90 - 120 min in case of allergy. Anticoagulation drugs were generally suspended in low risk for thrombo-embolic events ($CHA_2DS_2VASc$ score < 3). Pocket was created at the beginning of the procedure. The cephalic vein was preferred as the first intention. Right ventricular apex (RVA) was the preferred lead position. Lead fixation was done by non absorbable sutures. Pocket was irrigated by infusion of Gentamycin. Generator was not fixed. The pocket and skin were closed by separate stitches using absorbable braided suture for the pocket and non absorbable braided suture for the skin.

### 2.4. Sampling Methods and Statistical Analysis

The sampling was non-probabilistic, consecutive and non-exhaustive. Statistical analysis was carried out using the Excel 2019 spreadsheet and SPSS version 23 software. The quantitative variables were presented as mean ± standard deviation, the qualitative data as proportions.

### 2.5. Ethical Considerations

The study was validated by the quality committee of Haute Correze hospital center

and the Limousin ethics committee.

## 3. Results

Over the study period of 90 months, a total of 303 first-time pacemaker implantations were carried out, *i.e.* a rate of 40 per year. The average age in the population was 79.7 ± 9.4 years (44 - 99 years) with a male predominance of 63.7% (n = 193). Atrioventricular block (2nd and 3rd degree) was the main indication for pacemaker implantation in 42.9% of cases (n = 130). Patients were most often implanted with a dual-chamber pacemaker (57.7%, n = 175). In our series, there was no use of a back-up temporary stimulation during implantation. The approach was most often cephalic in 72.6% of cases (n = 220), followed by the subclavian vein in 27.4% of cases (n = 84). The average fluoroscopy time was 7.9 min ± 2.4 (1 - 43). The average irradiation dose in gray/cm$^2$ was 12.4 ± 9.3 (0.22 - 117.5). The median irradiation being 15.6. The average length of hospitalization was 7 ± 4 (2 - 26) days. *Baseline characteristics of the patients were summarized in* Table 1.

Table 1. Baseline characteristics of the population.

| Variables | Frequency (%)<br>N = 303 |
|---|---|
| **Indications** | |
| *Atrio-ventricular block* | 130 (42.9) |
| *Sinus node dysfunction* | 43 (14.2) |
| *Slow-rate atrial fibrillation* | 50(16.5) |
| *Tachy-brady syndrome* | 61 (20.1) |
| *Alternating Bundle-branch block* | 10 (3.3) |
| Others | 9 (3.0) |
| **Pacemaker types** | |
| *Simple chamber* | 129 (42.5) |
| *Double chamber* | 175 (57.7) |
| **Veinous access** | |
| *Cephalic* | 220 (72.6) |
| *Subclavian* | 84 (27.7) |

The overall complications rate at one year in our series was 12.9% (n = 39). These complications are distributed as follows: Lead dislodgment in 8.2% (n = 25), hematomas 3.6% (n = 11) all without clinical consequences, pneumothorax 0.7% (n = 2), both cases of pneumothorax were minimal and did not require specific care, superficial infection 0.3% (n = 1). Leads dislodgement occurred after a median time of 18 days (IQR: 3 - 36). The earliest dislodgement was observed on D0 and the latest on D207. No serious complications (complications requiring

transfer in intensive care or causing death) were recorded. Figure 1 *presents overall complications of our series.*

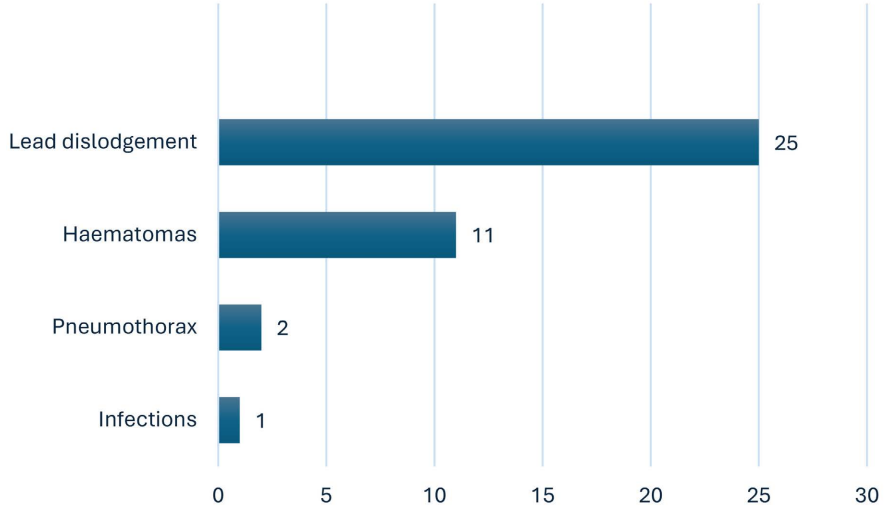


Figure 1. Post-procedural complications after pacemakers implantation.

The average atrial threshold at implantation/first control/last follow-up was 0.7/1.3/0.8 V, respectively. The average ventricular threshold at implantation/first control/last follow-up was 0.5/1.08/0.87 V, respectively. Figure 2 shows evolution of atrial and ventricular threshold. The average atrial detection at implantation/first control/last follow-up was 3.2/2.3/2.05 mv, respectively. The average ventricular detection at implantation/first control/last follow-up was 10.3/11.03/10.8 mv. Figure 3 shows evolution of atrial and ventricular detections. The average atrial impedance at implantation/first control/last follow-up was 610/457/457 ohms. The average ventricular impedance at implantation/first control/last follow-up was 754/547/563 ohms. Figure 4 shows evolution of atrial and ventricular impedances.

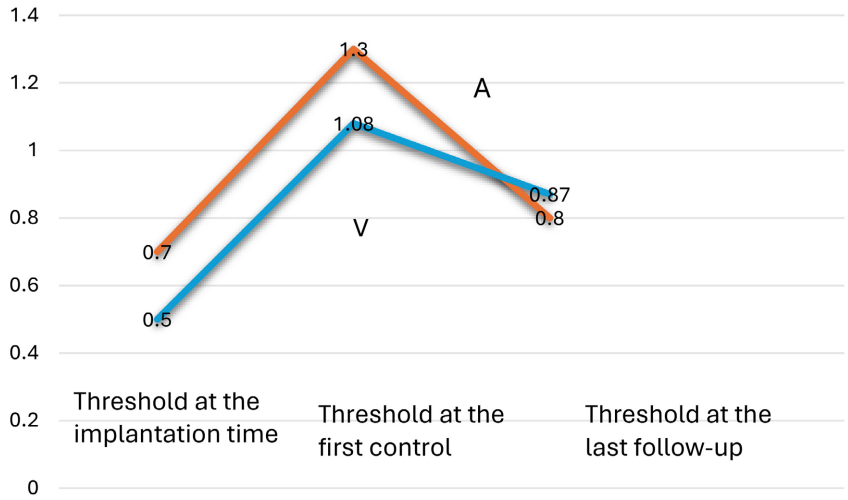


Figure 2. Evolution of the stimulation threshold during follow-up.

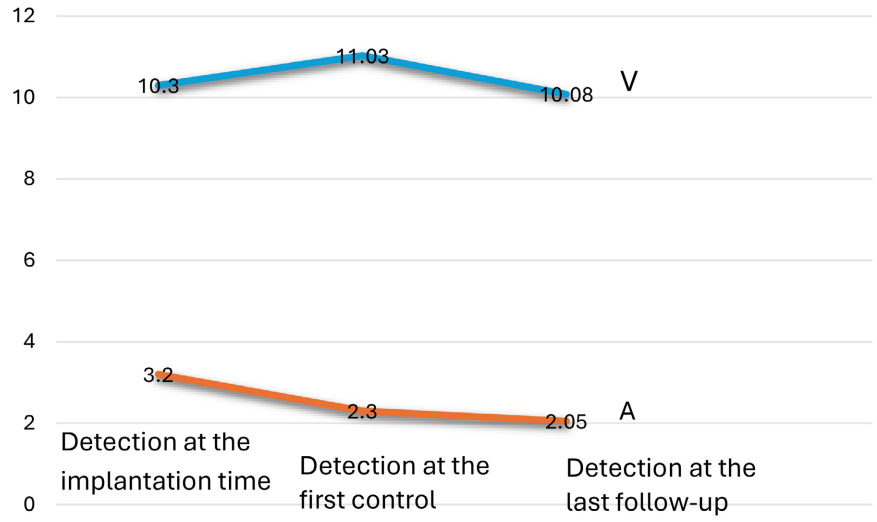


**Figure 3.** Evolution of the detection during follow-up.

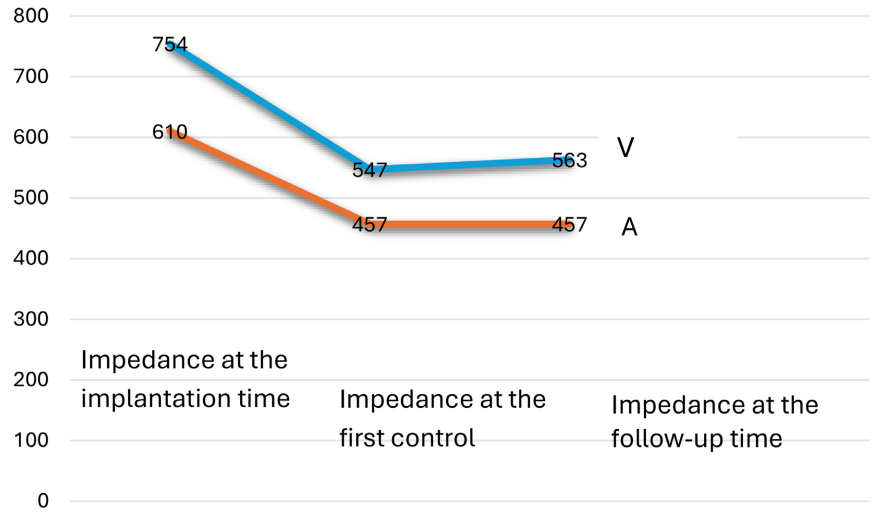


**Figure 4.** Evolution of the impedance during follow-up. A: Atrial lead; V: Ventricular lead.

## 4. Discussion

Pacemaker implantation is a well codified activity in cardiac centers. The peripheral hospitals faced to the increase number of procedures over the time [2]. Our aim was to evaluate the pacemaker's activity in general and more specifically to assess the post-procedural complications at the Haute Correze Hospital Center (HCHC). We conduct a longitudinal retrospective study over the last 7 years in the cardiology department of HCHC. A total of 303 implantations of pacemakers were included. The overall complications rate at one year in our series was 12.9%. These complications are distributed as follows: Leads dislodgement in 8.2%, minor hematomas 3.6%, pneumothorax 0.7% (not required drainage), superficial infection 0.3%. No serious complications were recorded.

The rate of overall complication slightly superior to the previous data generally ranged between 5% - 6% [6]-[8]. But with a sub-group comparison, we have no

major complications in our series compared to previous data of 3% - 4% for major complications after PM implantations [6]-[8]. Even if the global complications is well correlated to the procedure volume of the center/operator, the lack of major complication is an important result of safety for a small hospital [2]. Nevertheless, a significant limit of this interpretation is the fact that previous studies included all cardiac implantable electronic devices (defibrillators and cardiac resynchronization therapy) which have more risk of major complications compared to pacemakers only [9] [10].

Lead dislodgment was the main complication, the rate in our series is superior than reported data (1.2% - 3.3%) [11]-[13]. Some predictors of lead dislodgment are: Atrial lead position, age at implantation, female gender, body mass index [4] [12]-[17]. One important factor of lead dislodgment in our study is probably advanced age of patients (mean age of 80 years) and specifically frailty. Even if raising the upper extremity on the side of the CIED above the head is no associated with lead dislodgement, early patient agitation after implantation with inappropriate movements of the limbs and chest, traumatic events, and manipulations in the area of the CIED can cause possible Twiddler's syndrome, an important cause of leads dislodgement [18] [19]. The rate of hematoma was low in our study. The literature reported an incidence of 0.2% to 16% [2]. Our protocol of hemostasis and adequate management of patient with anticoagulant/antiplatelet drug contribute to this low incidence. Incidence of pneumothorax is also low in our series due to the preferred cephalic vein than subclavian access for implantation.

There were no major infections in our cohort, only one superficial pocket infection was found and required a short antibiotic therapy. This rate was inferior to reported data (0.6% - 3.4%) [2]. Infection and particularly infective endocarditis is a dreadful complication of all cardiac implantable electronic device [2]. Standardized protocol proposed by EHRA could help to prevent this complication [2]. The low incidence of infection in a peripheral center is a good indicator of safety. Even if, the use of local antibiotic in the pocket is not present in current guidelines for pacemaker implantation except for some cases of generator replacements or lead revision for which antibacterial envelope is required [20], we hypothesized that our protocol which includes infusion of antibiotic by gentamycin in the pocket could contribute for few rate of infection in our series. A meta-analysis conducted by Feng-Guang *et al.* in 2017, confirmed that pocket irrigation with antibiotics were effective for reducing pocket infection. In fact, 10 studies including 5467 patients undergoing cardiac implantable electronic devices implantations. Pooled infection rates were 1.48 and 3.49% respectively for medication and saline irrigation groups. Meta-analysis showed that medication irrigation conferred protection to pocket infection. Subgroup analysis showed that antibiotics against staphylococcus aureus, rather than non-antibiotics (antiseptics) exerting the protection [21].

## 5. Conclusion

Pacemaker implantation is safe at the Haute Correze Hospital Center with a relative low rate of specific complications particularly low rate of post-procedural

infections. The peripheral hospital should remain a focal point of this activity in order to respond more quickly to the needs of the populations.

## Acknowledgements

The authors thank the paramedical staff (Nathalie Besse and Elodie Chassain) who contributed to data selection.

## Authors Contributions

Conception of the Study: MT, AB, BGM. Data Analysis and Manuscript Writing: MT. Critical Appraisal: All the authors and Alice Ossa.

## Conflicts of Interest

The authors have no conflicts of interest to declare.

## References

[1] Timmis, A., Townsend, N., Gale, C., Grobbee, R., Maniadakis, N., Flather, M., *et al.* (2018) European Society of Cardiology: Cardiovascular Disease Statistics 2017. *European Heart Journal*, **39**, 508-579.

[2] Burri, H., Starck, C., Auricchio, A., Biffi, M., Burri, M., D'Avila, A., *et al.* (2021) EHRA Expert Consensus Statement and Practical Guide on Optimal Implantation Technique for Conventional Pacemakers and Implantable Cardioverter-Defibrillators: Endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin-American Heart Rhythm Society (LAHRS). *EP Europace*, **23**, 983-1008. https://doi.org/10.1093/europace/euaa367

[3] Reynolds, M.R., Cohen, D.J., Kugelmass, A.D., Brown, P.P., Becker, E.R., Culler, S.D., *et al.* (2006) The Frequency and Incremental Cost of Major Complications among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators. *Journal of the American College of Cardiology*, **47**, 2493-2497. https://doi.org/10.1016/j.jacc.2006.02.049

[4] Ellenbogen, K.A., Hellkamp, A.S., Wilkoff, B.L., Camunãs, J.L., Love, J.C., Hadjis, T.A., *et al.* (2003) Complications Arising after Implantation of DDD Pacemakers: The MOST Experience. *The American Journal of Cardiology*, **92**, 740-741. https://doi.org/10.1016/s0002-9149(03)00844-0

[5] Kirkfeldt, R.E., Johansen, J.B., Nohr, E.A., Jorgensen, O.D. and Nielsen, J.C. (2013) Complications after Cardiac Implantable Electronic Device Implantations: An Analysis of a Complete, Nationwide Cohort in Denmark. *European Heart Journal*, **35**, 1186-1194. https://doi.org/10.1093/eurheartj/eht511

[6] Nowak, B., Misselwitz, B., Erdogan, A., Funck, R., Irnich, W., Israel, C.W., *et al.* (2009) Do Gender Differences Exist in Pacemaker Implantation—Results of an Obligatory External Quality Control Program. *Europace*, **12**, 210-215. https://doi.org/10.1093/europace/eup312

[7] Tobin, K., Stewart, J., Westveer, D. and Frumin, H. (2000) Acute Complications of Permanent Pacemaker Implantation: Their Financial Implication and Relation to Volume and Operator Experience. *The American Journal of Cardiology*, **85**, 774-776. https://doi.org/10.1016/s0002-9149(99)00861-9

[8] Eberhardt, F. (2005) Long Term Complications in Single and Dual Chamber Pacing Are Influenced by Surgical Experience and Patient Morbidity. *Heart*, **91**, 500-506.

https://doi.org/10.1136/hrt.2003.025411

[9] Uslan, D.Z. (2007) Permanent Pacemaker and Implantable Cardioverter Defibrillator Infection. *Archives of Internal Medicine*, **167**, 669-675. https://doi.org/10.1001/archinte.167.7.669

[10] Lee, D.S., Krahn, A.D., Healey, J.S., Birnie, D., Crystal, E., Dorian, P., *et al.* (2010) Evaluation of Early Complications Related to De Novo Cardioverter Defibrillator Implantation. *Journal of the American College of Cardiology*, **55**, 774-782. https://doi.org/10.1016/j.jacc.2009.11.029

[11] Cheng, A., Wang, Y., Curtis, J.P. and Varosy, P.D. (2010) Acute Lead Dislodgements and In-Hospital Mortality in Patients Enrolled in the National Cardiovascular Data Registry Implantable Cardioverter Defibrillator Registry. *Journal of the American College of Cardiology*, **56**, 1651-1656. https://doi.org/10.1016/j.jacc.2010.06.037

[12] Dębski, M., Ulman, M., Ząbek, A., Boczar, K., Haberka, K., Kuniewicz, M., *et al.* (2018) Lead-Related Complications after DDD Pacemaker Implantation. *Kardiologia Polska*, **76**, 1224-1231. https://doi.org/10.5603/kp.a2018.0089

[13] Udo, E.O., Zuithoff, N.P.A., van Hemel, N.M., de Cock, C.C., Hendriks, T., Doevendans, P.A., *et al.* (2012) Incidence and Predictors of Short- and Long-Term Complications in Pacemaker Therapy: The FOLLOWPACE Study. *Heart Rhythm*, **9**, 728-735. https://doi.org/10.1016/j.hrthm.2011.12.014

[14] Gadler, F., Valzania, C. and Linde, C. (2014) Current Use of Implantable Electrical Devices in Sweden: Data from the Swedish Pacemaker and Implantable Cardioverter-Defibrillator Registry. *Europace*, **17**, 69-77. https://doi.org/10.1093/europace/euu233

[15] Ghani, A., Delnoy, P.P.H.M., Ramdat Misier, A.R., Smit, J.J.J., Adiyaman, A., Ottervanger, J.P., *et al.* (2014) Incidence of Lead Dislodgement, Malfunction and Perforation during the First Year Following Device Implantation. *Netherlands Heart Journal*, **22**, 286-291. https://doi.org/10.1007/s12471-014-0556-6

[16] Tseng, A.S., Shipman, J.N., Lee, J.Z., Mi, L., Amin, M., Killu, A.M., *et al.* (2019) Incidence, Patterns, and Outcomes after Transvenous Cardiac Device Lead Macrodislodgment: Insights from a Population-Based Study. *Heart Rhythm*, **16**, 140-147. https://doi.org/10.1016/j.hrthm.2018.07.026

[17] Qin, D., Filippaios, A., Murphy, J., Berg, M., Lampert, R., Schloss, E.J., *et al.* (2022) Short- and Long-Term Risk of Lead Dislodgement Events: Real-World Experience from Product Surveillance Registry. *Circulation*: *Arrhythmia and Electrophysiology*, **15**, e011029. https://doi.org/10.1161/circep.122.011029

[18] Takeda, T., Tsubaki, A., Ikeda, Y., Kato, R., Kojima, S. and Makita, S. (2023) Impact of Raising the Upper Extremity Siding Cardiac Implantable Electrical Devices on Postoperative Safety. *Journal of Arrhythmia*, **39**, 586-595. https://doi.org/10.1002/joa3.12884

[19] Mlynarski, R., Mlynarska, A., Joniec, M., Gladysz-Wanha, S., Honkowicz, M., Stachanczyk, J., *et al.* (2022) Predictors of Early Cardiac Implantable Electronic Device Lead Dislodgement in the Elderly. *International Journal of Environmental Research and Public Health*, **19**, Article 14766. https://doi.org/10.3390/ijerph192214766

[20] Tarakji, K.G., Mittal, S., Kennergren, C., Corey, R., Poole, J.E., Schloss, E., *et al.* (2019) Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. *New England Journal of Medicine*, **380**, 1895-1905. https://doi.org/10.1056/nejmoa1901111

[21] Kang, F., Liu, P., Liang, L., Lin, Y., Xie, S., He, Y., *et al.* (2017) Effect of Pocket Irrigation with Antimicrobial on Prevention of Pacemaker Pocket Infection: A Meta-Analysis. *BMC Cardiovascular Disorders*, **17**, Article No. 256. https://doi.org/10.1186/s12872-017-0689-9

## Abbreviations

**CIED:** Cardiac Implantable Electronics Devices
**EHRA:** European Heart Rhythm Association
**HCHC**: Haute Correze Hospital Center
**IQR:** Interquartile Range
**RVA:** Right Ventricular Apex
**SPSS:** Statistical Package of Social Sciences