How to decrease the cost of pacemaker infection treatment by adopting seemingly costly innovation? A budget impact analysis of a leadless pacemaker implantation

Paweł Syska[1], Michał M Farkowski[1], Monika Raulinajtys-Grzybek[2], Aneta Lis[3], Mariusz Pytkowski[1]

[1]2nd Department of Heart Arrhythmia, National Institute of Cardiology, Warszawa, Poland
[2]Department of Management Accounting, Warsaw School of Economics, Warszawa, Poland
[3]Hospital-based Health Technology Assessment Team, National Institute of Cardiology, Warszawa, Poland

Correspondence to:
Michal M Farkowski, MD, PhD,
2nd Department of Heart Arrhythmia,
National Institute of Cardiology,
Alpejska 42,
04–628 Warszawa, Poland,
phone: +48 22 343 40 02,
e-mail: mfarkowski@gmail.com

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INTRODUCTION

Infections are among the most dangerous and costly complications of cardiac implantable electronic devices (CIED) [1–3]. In order to prevent those complications and decrease their costs, several technologies were studied and described [1, 4, 5]. However, a significant proportion of risk factors for CIED-related infection, such as previous history of CIED infection, advanced renal disease, generator exchange, or abdominal localization of the device generator, cannot be accounted for or modified [1]. Leadless pacemakers (LPM) are a promising innovation for patients at high and extremely high risk of CIED-related infection [6–8]. Unfortunately, their high costs and the lack of reimbursement may lead to suboptimal decisions to avoid LPM implantation in clinically sound situations, which, in turn, may generate a series of even more costly complications.

This study aimed to calculate the budgetary impact of a belated decision to implant a leadless pacemaker in a patient at an extremely high risk of pacemaker-related infection from the perspective of the hospital and the public payer.

METHODS

An economic model was developed to assess the budgetary impact of a delayed implantation of an LPM in a "real-world scenario" (RwS) in opposition to a potential "optimal scenario" (OpS). The perspectives of both the National Health Fund (NHF) and the hospital were considered.

Briefly, in the RwS, an 89-year-old female with an epicardial VVI pacemaker implanted in 2009 and with an extremely high risk of infection (abdominal location of the generator due to occlusion of the superior vena cava after an episode of kidney failure requiring temporary hemodialysis, with frailty syndrome, end-stage chronic kidney disease, on a vitamin K antagonist) was scheduled for a generator exchange in 2018. Despite the apparent risk of infection, LPM was considered but not implanted due to the lack of precise reimbursement criteria for such a procedure at that time. In 2020, a series of complications occurred due to pocket infection (Supplementary material, *Figure S1*), including surgery of the entrapped umbilical hernia, resulting in extraction of the pacemaker and implantation of LPM (Micra TPS, Medtronic, Mounds View, MN, US). In a hypothetical OpS, LPS would have been implanted instead of generator replacement, and the aforementioned complications would have been avoided. The clinical course, clinical decisions, and timing in both scenarios had been provided in Supplementary material, *Table S1*.

NHF tariffs were derived from Diagnosis-Related Groups (DRGs), as well as Ambulatory-Patient Groups (APGs), and those tariffs are universal for hospitals having NHF contracts. In cases when the actual cost exceeds the DRG value more than threefold (e.g. both hospitalizations for LPM implantation), the price is set individually.

The direct and indirect medical costs incurred by the hospital (e.g. cost of medical

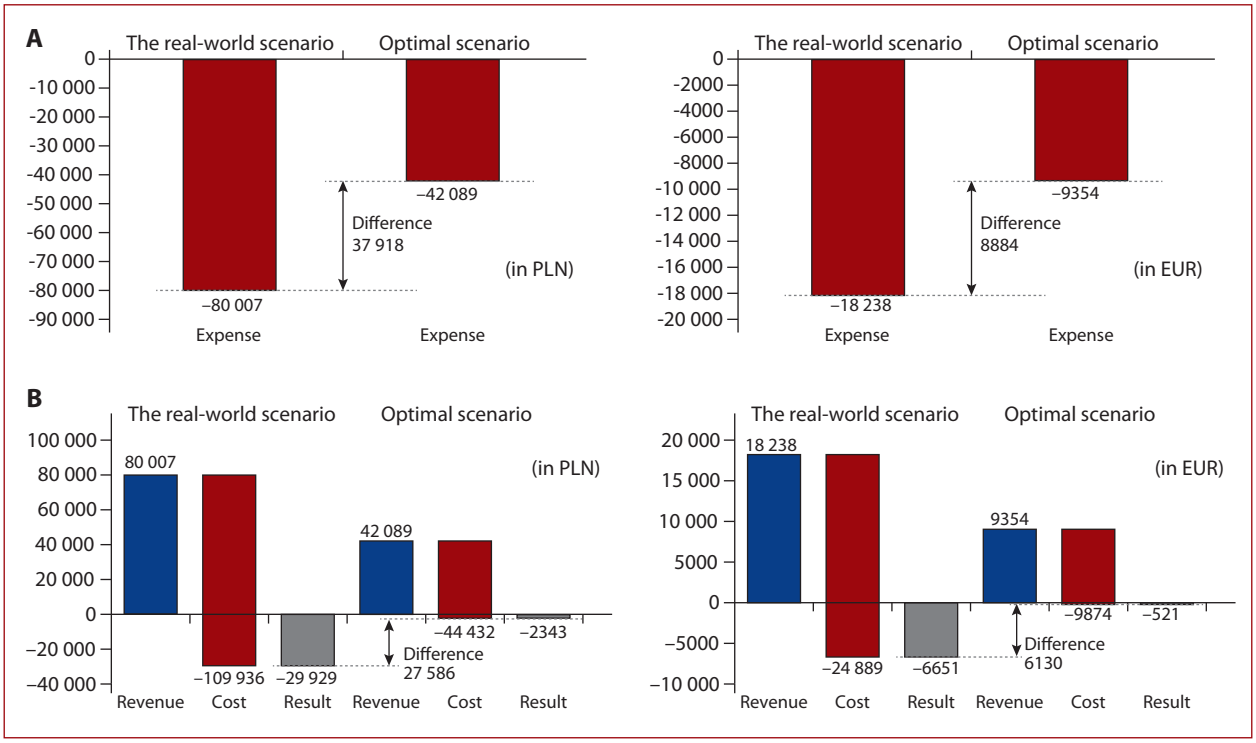

Figure 1. The budget impact of a belated decision to implant a leadless pacemaker calculated from the National Health Fund (**A**) and hospital (**B**) perspective

or diagnostic procedures, general cost of a day of hospital stay) were calculated based on the data obtained directly from the hospital costing system. The cost of lost benefits has not been included in the model due to the budget cap in Polish hospitals.

The structure of the model and its conformity with the Polish clinical practice were validated by the co-authors. A fixed exchange rate was used for the conversion of PLN into EUR (1 EUR = 4.50 PLN). The model was developed according to the ISPOR Budget Impact Analysis Good Practice Guidelines using Microsoft Office Excel software [9].

The study was approved by the Local Bioethics Committee (IK.NPIA.0021.41.1970/22).

RESULTS AND DISCUSSION

Model inputs with associated sources were presented in Supplementary material, *Table S2*. The budgetary impact of the belated decision to implant an LPM from the NHF and hospital perspectives was presented in Supplementary material, *Table S3* and *S4*, respectively. Figure 1 presents the main outcomes of the study.

The main results of our study are: (1) in comparison to the "optimal scenario", the "real-world scenario" was related to a substantial loss for both the NHF (49% higher expenses) and the hospital (10-fold increase!); (2) the main driver of the public payer's costs were additional hospitalizations due to infectious complications; (3) the main driver of the hospital costs was the length of the hospitalization.

The costs of CIED-related infections are high both in Europe and in North America [3, 10, 11]. Typical components of those costs comprise long hospital stays, costs of new devices, and transvenous lead extraction (TLE) procedures. This was shown to be true also for Poland [2]. However, that particular study excluded patients implanted with LPM, another considerable cost for Polish hospitals [12].

Our study showed that the potential "optimal scenario" would have been beneficial both to the NHF and the hospital. The main difference between the analyzed scenarios was an assumption that several costly complications could have been avoided by implanting the high-cost but low-risk LPM earlier rather than proceeding with the exchange a low-cost but extremely high-risk pacemaker located in the abdomen. One must bear in mind that those decisions were considered during a time when it was unclear at best if the public payer would cover high individual costs of LPM implantation. The COVID-19 pandemic was another important factor. The patient's contact with healthcare providers was hindered, which contributed to advancing the stage of infection at the second hospitalization [13, 14].

The high costs of many innovations may limit their swift implementation despite convincing clinical evidence. A hospital-based health technology assessment can provide crucial and up-to-date information on the effectiveness, safety, costs, and benefits/pitfalls of adoption of an innovative medical technology [15]. This systematic information may help and guide hospital management to adopt an innovation even before NHF reimbursement decision is made.

We would like to emphasize that our study should be interpreted with caution. It is an economic evaluation of potential consequences of medical decision-making in the

context of reimbursement uncertainty rather than clinical evidence of the superiority of one mode of permanent pacing over the other.

Limitations

This was a budgetary impact calculation of a potential scenario in opposition to a real-life situation based on the data from a case of a single patient with pacemaker-related infection treated in a tertiary care cardiological center. The clinical course of the case, clinical and administrative decisions, and, last but not least, costs might differ in other centers.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska

Article information

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