Assessment of prevalence of skin allergic reactions and systemic hypersensitivity reactions in patients with implantable devices used in electrotherapy of cardiovascular diseases

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Abstract:
Implantable endovascular devices significantly reduce mortality and improve prognosis in patients with chronic cardiovascular disorders. These include pacemakers, cardioverter-defibrillators and resynchronization devices. The use of these devices is perceived as safe and clinically effective. However, there have been reports in the literature of individual cases of skin allergic reactions and systemic hypersensitivity reactions in relation to the implanted devices. The aim of the study was to assess the prevalence of these complications in electrotherapy procedures. The study group included 1683 patients who underwent the implantation of the electrotherapy device in the years 2008–2018 at the Cardiology Department of the Provincial Hospital in Wloclawek. During the follow-up, not a single case of skin allergic reaction or systemic hypersensitivity reaction to the implanted device was recorded. In the analyzed population in the whole observation period, 3 cases qualified for planned system removal were observed. In each of them, infectious aetiology was confirmed as the cause of complications, isolating the pathogen from intraoperative material.

Key words: pacemaker, cardioverter-defibrillator, cardiovascular implantable electronic devices, allergic reaction, hypersensitivity, antigen, hapten

Introduction

In modern electrotherapy, intravascular implantable devices have found wide application in the treatment of many disorders. They significantly reduce mortality and improve prognosis in patients with cardiovascular disorders. This heterogeneous group of devices includes pacemakers (PM), implantable cardioverter defibrillators (ICD) and cardiac resynchronization device (CRT) [1]. They are collectively referred to as cardiovascular implantable electronic devices (CIEDs) [2]. More generally, this group can include also as less commonly used implantable loop recorder (ILR) and implantable cardiovascular monitor (ICM) [3].

The first pacemaker implantation in a patient took place on October 8th 1958 year. For over 50 years of experience gained this form of therapy is seen as a safe and clinically effective for large groups of patients. Only sporadic reports of a possible hypersensitivity reactions in response to the implanted stimulating system appear in scientific publications [4–8]. It is postulated that the basis of a contact allergic reaction is specific hypersensitivity of the patient's body to low molecular weight chemical compounds. These substances are often metals. They are referred to as haptens or incomplete allergens that only become fully reactive after binding to tissue or plasma proteins, re-

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sponsible for a cell-type allergic reaction. A typical clinical manifestation of an allergic reaction may be contact eczema around the pacemaker pocket. There are also possible pathologies like urticaria eruption at distant body locations or skin lesions with the type of allergic vasculitis. Individual cases of systemic reactions in the form of asthmatic state, anaphylactic shock or septic reaction have been described [9].

The main purpose of this research was evaluating the prevalence skin reactions or systemic hypersensitivity reactions in patients after implantation of the cardiovascular devices used in the electrotherapy procedures in cardiology.

Material and methodology

The study population consisted of patients undergoing cardiovascular electronic devices implantation procedure in the years 2008–2018 in the Department of Cardiology, Regional Hospital in Wloclawek, who remained under the long-term care outpatient cardiology clinic.

The total number of subjects was 1683. In this population, women constituted 41.6% (699 patients), while men 58.4% (984 patients). The average age of the patient at the time of enrollment was 65.7 years. The average follow-up period after implantation of the device to the end of observation was 4.7 (0.3–9.6) years.

Follow-up visits included patient's physical and physical examination, control of pacemaker function, and additional testing in cases deemed necessary.

Results

In the observation period, the dominant type of implantable devices was PM. There was a relatively small share of implanted cardioverter-defibrillators and resynchronizing devices in the observed population. They constituted only 1.8% of the total number of treatments (31 devices). 98.2% of implanted devices were pacemakers (1652 devices).

Among them, 62.7% were double-chamber devices (DDD), while 37.3% were single-chamber devices (VVI). In 5.2% of cases (87 patients), there was planned reimplantation of the device due to elective replacement indication (ERI).

In 2 cases, implantation of cardiovascular electronic devices was performed in patients with a history of nickel allergy. In both cases, dedicated systems without nickel (100% titanium) were used. In one case, an additional gold-coated device (CD) was used. Both treatments performed without complications.

The average time between consecutive follow-up visits to the clinic was 217 days. During the follow-up, not a single case of skin allergic reaction or systemic hypersensitivity reaction to the implanted device was recorded. In the analyzed population, 3 cases qualified for elective device explants due to lead dependent infective endocarditis (LDIE) or local infection of the pacemaker pocket were registered throughout the entire follow-up period. In 2 cases, the cardiovascular device was removed in the early period after implantation. In one case, as a late complication, the pacemaker was removed with cardiac surgery protection. In each of them, infectious aetiology was confirmed as the cause of complications, isolating the pathogen from intraoperative material. A relatively low percentage of reported infectious complications could have resulted from the possibility of migrating some cases directly to reference centres.

Discussion

In our analysis of the incidence of hypersensitivity-type reactions to intravascular implantable devices used in electrotherapy procedures in cardiology, we confirmed the safety of these devices.

The most sensitizing metal of the European population is nickel [10]. This may affect up to 17% of the female population and 3% of the male population. Cobalt, chromium and palladium are other metals in the frequency of causing an allergic reaction [11]. Based on available scientific publications based on analysis using radiological fluorescence spectrometry (XRS), it can be assumed, however, that the main component of CIEDs is titanium (Ti 99.85–100.00%). Depending on the manufacturer and model of the device used, there may also be a small amount of other metals such as iron (Fe 0.02–0.05%), nickel (Ni 0.01–0.02%), tin (Sn 0.04–0.09%), antimony (Sb 0.051–0.057%), molybdenum (Mo 0.01–0.02%) and manganese (0.04–0.06%) [6].

The content of potential allergens in manufactured cardiovascular implantable electronic devices is thus marginally low or even zero, which is basis of good tolerance of the implants used in patients and the lack of complications of allergic reactions in the long term follow-up.

Conclusions

Based on detailed clinical observations, it can be concluded that the metal alloy used for the production of cardiovascular implantable electronic devices is

well tolerated by the patients' body. Only in unique situation can it cause an allergic reaction, as indicated by episodic case reports in the literature [7, 8].

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