Economic implications of infections of implantable cardiac devices in a single institution

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Abstract

Introduction: The use of medical devices, such as cardiac pacemakers, prosthetic heart valves and vascular prostheses, has become a routine treatment procedure in cardiovascular medicine. Unfortunately, bacterial infections of these devices are a serious and sometimes life-threatening for the patient, necessitating explantation. Despite implementing different prophylactic strategies to avoid contamination of the device, infections do occur. This study analysed the additional hospital costs associated with managing cardiac device infections, with special focus on cardiac pacemakers/defibrillators, prosthetic heart valves and vascular prostheses. Methods: Out of more than 2000 operations performed in our institution in 2006, we had 462 implantations/replacements of cardiac pacemakers/implantable cardioverter defibrillators (ICDs), 577 valve replacement procedures and 613 vascular operations. Among these, we analysed all patients who received operations because of an infection of their cardiac or vascular device. Our investigations focussed on standard parameters regarding additional hospital costs, including length of stay in hospital, required time in the operating room and time in the intensive care unit. Results: In 2006, we had nine cases (n = 9) of prosthetic valve endocarditis in our hospital. The average length of stay in hospital for these patients was 25 days, resulting in €72 096 of additional hospital costs per case. Infection of vascular prostheses (n = 6) leads to €35 506 per case and 28 days in the hospital. If an infection of cardiac pacemakers (n = 7) does occur, the therapy causes a mean additional hospital cost of €7091. Conclusion: Cardiac device infections are serious and sometimes life-threatening. Therapy and eradication are difficult and protracted and cause high additional hospital costs. Based on our statistical data and the mean incidence of cardiac device infections, we presume for Germany between €38 and €140 million in additional hospital costs per year are incurred by infections of implantable cardiovascular devices. Active surveillance and establishment of a central register with documentation of every implantation and the occurrence of any infection can only realise detailed estimates of the economic damage caused by infection of cardiovascular implants. In consideration of the economic consequences, successful strategies must be developed to reduce the incidence of infections.

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Keywords: Cardiac device; Infection; Costs; Economic damage

1. Introduction

The use of cardiovascular implants is steadily increasing in modern medicine. However, it is precisely this usage of foreign materials that leads to an increase in infection, a serious complication [1]. Infections of medical implants are among the most dangerous complications, because an effective therapy does not exist and explantation of the device seems to be the only acceptable solution, with all of the related consequences [2,3]. Furthermore, the bacteria causing an implant infection can adhere irreversibly to the surface of the foreign body, disturbing the natural healing process [4]. Most of the bacteria that cause implant infections do not live in a planktonic form, but rather in so-called biofilm communities, which are an extremely flexible, efficient and universal form of life; so it is still rudimentary as compared with multicellular organisms [5]. Therefore, bacteria organised in biofilms show a significantly higher resistance to antibiotics [6,7], a result of reduced penetration of the antibiotic, changes in growth rate and gene expression and a modified micro-environment within the matrix. In addition, the human immune system is less effective against bacteria living in these communities.

Therefore, the only effective treatment option of infections of cardiovascular implants, such as cardiac pacemakers/defibrillators, prosthetic heart valves and vascular prostheses, is surgical explantation [8,9]. This procedure leads to a large, potentially life-threatening...
event for the patient, and it also increases health-care costs. It is extremely difficult to find any publications concerning such acute or chronic infections because there is no accurate database with information about cardiac device infections. In addition, the incidence of implant infections is still considered as a centre-specific complication, and so it is often not documented with appropriate information. To better understand the economic impact of cardiac device infections and their associated management, we have tried to estimate and analyse the corresponding costs.

2. Methods

This single-institution study was conducted at the Department of Thoracic, Transplant, and Cardiovascular Surgery with more than 2300 patients undergoing cardiothoracic and vascular operations per year. The incidence in our tertiary-care hospital for prosthetic valve infection is 0.7%, for infections after implantation of a vascular prosthesis 4.8% and for infections after pacemaker implantation 1.1%. Due to the complex and difficult operating conditions, patients with infection of their cardiovascular implant are transferred to our department for operation. We retrospectively investigated the surgical procedures of the year 2006 and included all patients with infection of their implanted cardiovascular device.

2.1. Definition and case finding

Among our group of patients, we identified those with re-operation due to infection of their cardiovascular device. We included patients with prosthetic heart-valve endocarditis, detected by positive blood cultures, echocardiographic detection of vegetations on the valve or computer tomographic (CT)-morphological evidence of an abscess formation with enhancement of contrast agent in the area of the implanted prosthetic valve. Similar criteria were used for patients with infection of an implanted pacemaker/implantable cardioverter defibrillator (ICD): positive blood culture, echocardiographic detection of vegetations on the lead, abscess formation or transcutaneous penetration of the aggregate. We identified infection of an artificial vascular prosthesis in patients with positive blood cultures or CT morphological evidence for prosthetic infection.

2.2. Data collection

Patient information concerning age, gender and infection within the first year were transferred to our database. The postoperative length of stay in hospital was also recorded in whole days, calculated from the date of operation, and the duration was divided into time in the intensive care unit (ICU), the intermediate care unit (IMC) and the general ward. The required additional surgery due to implant infection and the associated costs were provided by the hospital’s finance department, and the latter was based on the Institute’s German manual for the billing system at hospital. The data were entered into a Microsoft Excel 97 spreadsheet via Windows 6.0 and analysed. All data are presented as arithmetic means ± standard deviation.

2.3. Costs

To estimate the economic impact of the implant infections for Germany, we extrapolated our collected data and average costs of the various infections using the incidence of implant infections per year stated in the literature and the number of performed implantations. These are only the average hospital costs that are incurred at our department, and neither outpatient costs nor costs of assigned hospitals or rehabilitation clinics were considered. Similarly, because of the different references regarding the incidence, we emphasise again that these data only represent a theoretical assessment of the economic consequences of infections of cardiovascular devices.

3. Results

In 2006, at the Medical School Hannover, we performed 577 heart-valve operations, 462 pacemaker/ICD operations and 613 cases of vascular surgery. The following patient data, as well as the costs incurred due to infection of the implants, are summarised in Table 1 and Fig. 1. The microbial diversity of various infections was not examined, as we focussed specifically on the economic impact of these infections.

3.1. Length of stay and costs

3.1.1. Prosthetic valve endocarditis

Within the patient population operated at Medical School Hannover, nine patients required re-operations because of an infection of the implanted artificial or biological prosthetic heart valve. In six patients, an artificial aortic valve prosthesis was infected \((n = 4\) for mechanical valve prosthesis, \(n = 2\) for biological prosthesis); in three patients, the infected prosthesis was in mitral position \((n = 2\) for mechanical valve prosthesis, \(n = 1\) for biological prosthesis). Four patients were male and five were female, with an average age of 61.6 ± 15.9 years. Six of these patients developed an early infection of the prosthesis, which means within the first 12 months after implantation. The repeat operation for a prosthetic infection had an average hospital stay of 25 ± 27 days.
In detail, these stays incurred 18 ± 22 days on ICU, 2 ± 4 days on intermediate care and 6 ± 4 days on general ward. The resulting costs for hospital care of these patients amounted to an average of €27 305 ± 30 632, in addition to the mean operating costs of €22 864 ± 27 869, anaesthesia costs of €252 1 ± 1423 and costs for laboratory tests and blood products of €14 875 ± 13 302. In summary, the average total cost per patient with an infected valve prosthesis was €72 096 ± 53 524, equivalent to €2871 per day in the hospital.

3.1.2. Infection of vascular prostheses

In 2006, we operated on six patients because of infection of their vascular prostheses. Five patients were male, and one was female, with a mean age of 61.2 ± 13.0 years. In two cases, the appearance of implant infection was during the first year after surgery, and in other cases it was at a later date. The medical care of these vascular prostheses infections caused an average hospital stay of 28 ± 17 days. These patients spent an average of 1 ± 1 days in the ICU, 1 ± 2 days in IMC and 25 ± 14 days in the general ward. In addition to the costs of inpatient care of €10 716 ± 11 937, we calculated €15 472 ± 18 618 of operation costs, €1781 ± 1671 of anaesthesia costs and €4901 ± 4611 for laboratory services and blood products. Therefore, the average of total cost per patient with infected vascular prosthesis amounts to €35 506 ± 30 198, or €1291 per day in the hospital.

3.1.3. Infection of cardiac pacemakers

Of our seven patients with infected dual-chamber pacemaker, five were male and two were female, with a mean age of 77.0 ± 7.3 years. An early infection during the first 12 months after implantation occurred in three of these cases. The average time spent in the hospital after surgical treatment was 10 ± 5 days, mostly in the general ward. The costs for inpatient care were €2141 ± 1094, together with average operating costs of €3216 ± 1525, costs for anaesthesia of €540 ± 158 and costs for laboratory tests of €334 ± 111, giving a total of €7091 ± 3180.

3.1.4. Cases without infection

In this work, the additional costs incurred due to infection of cardiovascular implants should be determined, which would not arise from a properly functioning device. Apart from this, the costs resulting from elective surgery of the used implants have been identified. During the same observation period, these control cases caused the following costs: single-valve replacement (n = 148) €15 638 ± 5736; implantation of a vascular prosthesis (n = 68) €10 394 ± 5736; and replacement of a double-chamber pacemaker (n = 20) €4424 ± 2262.

3.2. Estimated economic implications for Germany

3.2.1. Prosthetic valve endocarditis

Infections of artificial heart valves represent 7—25% of all cases of endocarditis in the Western world. The lethality of prosthetic valve endocarditis is 20—25% because of deterioration of the haemodynamic situation and bacterial embolism. There are both early (within the first year) and late infections. The main causes of prosthetic valve endocarditis are coagulase-negative Staphylococcus, Staphylococcus aureus, streptococci or enterococci. The cumulative risk of prosthetic valve endocarditis is estimated to amount to 2%. In Germany, about 20 000 heart-valve operations are performed every year. An estimated 2% of these patients develop prosthetic valve endocarditis, affecting about 400 patients per year. With estimated hospital costs of €72 096 per case, this results in additional costs of €28 838 400 every year (Table 2).
of bacteria on the device via biofilm formation [10]. A number of host, biomaterial and microbial factors are involved in the initiation and persistence of device-related infections and consequently are responsible for treatment failures. The presence of tissue damage, leading to loss of local immunity and absence of tissue integration at the biomaterial–tissue interface is important for the initiation of an infectious process related to a device. These bacteria are highly resistant to antibiotics and host defence mechanisms [11]. For this reason, implant infections must be treated as a complicated and potentially life-threatening disease. Drug therapies often fail because of bacteria, and therefore, the surgical therapy remains as the only treatment option [12]. The required re-operation leads to enormous health-care costs, in addition to an increased mortality and lethality. Of course, it is difficult to capture the entire and true economic impact of implant infection. To our knowledge, there are no data about this reported in the literature. Therefore, we have tried to evaluate the total costs of each implant infection by calculating the costs for hospital stay, operating costs and laboratory costs. These additional costs and the duration of stay in the hospital are calculated from the average of patients who received operations because of device infection at our department in 2006. Based on this calculation, we performed a conservative extrapolation of the economic damage caused by infections of different cardiovascular implants. It is important to note again that this is just an example for a hypothetical projection because official figures do not exist for either the number of implantations or for the incidence of infections. Therefore, various estimates and data mentioned in the literature provided the basis for our calculation. The health-care costs for surgical treatment of cardiovascular device infections calculated in this way amount to between €40 million and 140 million per year in Germany. In reality, the real costs are probably even higher because these calculations only include costs arising in our hospital. Among the costs not included are treatments by other hospitals, outpatient and nursing services or rehabilitation, as well as less predictable costs caused by loss of earnings and disability.

Initially, based on our average hospital costs, we wanted to calculate the resulting economic damage caused by infection of cardiovascular infections on the Europe level and not only for Germany. We noticed that neither an international register for infections of cardiac valve prostheses, cardiac pacemakers/defibrillators or vascular prostheses exists nor exact health-care costs for implant infections for different countries.

### 3.2.2. Infection of vascular prostheses

About 0.5—5% of patients develop an infection of the graft within the first months after vascular replacement. Untreated, these infections lead to death or amputation of the affected limb. Regarding the spectrum of bacteria, staphylococci are still the most common germs, and the incidence of *S. aureus* and *Staphylococcus epidermidis* is roughly equal. However, Gram-negative germs are increasingly isolated. These are predominantly represented by *Escherichia coli*, followed by *Pseudomonas* strains. With about 18 000 implantations of artificial vascular prostheses in Germany per year, a suspected incidence of 0.5% would lead to €3 195 540 in yearly costs; an assumed incidence of 5% yields €31 955 400 of additional health-care costs per year (Table 2). Note that this calculation does not include PTFE prostheses and dialysis shunts, which would account for an additional 15 000 implantations per year.

### 3.2.3. Infection of cardiac pacemakers

The risk of infection after implantation of cardiac pacemakers and implantable defibrillators is indicated to be 1—12%. About half of patients with infections associated with pacemakers develop these from the pacemaker pocket, while the other half develop it from the electrode via haematogenous infection. Early and late infections can be distinguished. The most frequent bacteria are *S. aureus*, CoNS, viridans group streptococci and enterococci. With approximately 80 000 pacemaker implantations and about 15 000 ICD implantations in Germany per year, the declared incidence will lead to €6 736 450 and €80 905 800 of additional costs from implant infections (Table 2). This extrapolation includes only the calculated costs caused by infected dual-chamber pacemakers. The actual costs for infected implantable defibrillators, expected to be much higher, were not calculated by us, however, because during the observation period, we had no need for surgery due to an infected defibrillator system.

### 4. Discussion

The described implants, such as artificial heart valves, vascular prostheses and pacemaker/ICD, represent a large fraction of modern cardiovascular devices, and the patients depend on their flawless function. Following implantation of devices the host cell integration is necessary for uneventful healing. This process can be disturbed by successful adhesion of bacteria on the device via biofilm formation [10]. A number of host, biomaterial and microbial factors are involved in the initiation and persistence of device-related infections and consequently are responsible for treatment failures. The presence of tissue damage, leading to loss of local immunity and absence of tissue integration at the biomaterial–tissue interface is important for the initiation of an infectious process related to a device. These bacteria are highly resistant to antibiotics and host defence mechanisms [11]. For this reason, implant infections must be treated as a complicated and potentially life-threatening disease. Drug therapies often fail because of bacteria, and therefore, the surgical therapy remains as the only treatment option [12]. The required re-operation leads to enormous health-care costs, in addition to an increased mortality and lethality. Of course, it is difficult to capture the entire and true economic impact of implant infection. To our knowledge, there are no data about this reported in the literature. Therefore, we have tried to evaluate the total costs of each implant infection by calculating the costs for hospital stay, operating costs and laboratory costs. These additional costs and the duration of stay in the hospital are calculated from the average of patients who received operations because of device infection at our department in 2006. Based on this calculation, we performed a conservative extrapolation of the economic damage caused by infections of different cardiovascular implants. It is important to note again that this is just an example for a hypothetical projection because official figures do not exist for either the number of implantations or for the incidence of infections. Therefore, various estimates and data mentioned in the literature provided the basis for our calculation. The health-care costs for surgical treatment of cardiovascular device infections calculated in this way amount to between €40 million and 140 million per year in Germany. In reality, the real costs are probably even higher because these calculations only include costs arising in our hospital. Among the costs not included are treatments by other hospitals, outpatient and nursing services or rehabilitation, as well as less predictable costs caused by loss of earnings and disability.

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### Table 2

Estimated economical implications in Germany per year for prosthetic valve endocarditis, infection of vascular prostheses, and infection of cardiac pacemakers.

<table>
<thead>
<tr>
<th></th>
<th>Prosthetic valve endocarditis</th>
<th>Infection of vascular prostheses</th>
<th>Infection of cardiac pacemakers/defibrillators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total operations (non-infected/year)</strong></td>
<td>20 000</td>
<td>18 000</td>
<td>95 000</td>
</tr>
<tr>
<td><strong>Estimated costs (€/case)</strong></td>
<td>72 096</td>
<td>35 506</td>
<td>7091</td>
</tr>
<tr>
<td><strong>Estimated incidence (lowest in literature)</strong></td>
<td>2%</td>
<td>0.5%</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Estimated cases (per year)</strong></td>
<td>400</td>
<td>90</td>
<td>950</td>
</tr>
<tr>
<td><strong>Estimated costs (€/year)</strong></td>
<td>28 838 400</td>
<td>3 195 540</td>
<td>6 736 450</td>
</tr>
<tr>
<td><strong>Estimated incidence (highest in literature)</strong></td>
<td>—</td>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Estimated cases (per year)</strong></td>
<td>900</td>
<td>31 955 400</td>
<td>80 905 800</td>
</tr>
<tr>
<td><strong>Estimated costs (€/year)</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total costs (€/year)</strong></td>
<td>38 770 390–141 631 200</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

including less wealthy countries in Europe, where the cost structure may be different. However, on the basis of our data about the average hospital costs and the costs caused by infected implants, an extrapolation for these countries may also be possible, provided the necessary data are available and are set in relation to the attributable costs in Germany. Furthermore, there is no accurate database including every implant per year. This is also reflected by the fact of very different values about the incidence of cardiovascular infections available in the literature [13—17].

Therefore, the documentation and monitoring of patients after implantation is essential, at least on the national level. Moreover, an active surveillance of cardiac device infections would be desirable, particularly in the need of surgical intervention. The next step has to be the collection of clinical and epidemiological data, including additionally the microbiological spectrum, and the implementation of enhanced infection-control measures for the prevention of implant infections in the cardiovascular field. This procedure would reduce the patient’s individual risk of life-threatening complications and for health policy reasons, this targeted prophylaxis could minimise the economic effects that probably accounts for several million Euros.

References