Biofilm on Artificial Pacemaker: Fiction or Reality?

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Abstract

Cardiac pacing through cardiac pacemaker is one of the most promising alternatives in the treatment of arrhythmias, but it can cause reactions natural or complex reactions, either early or late. This study aimed to describe the scientific evidence on the risk of infection and biofilm formation associated with cardiac pacemaker. This is a study of integrative literature review. It included 14 publications classified into three thematic categories: diagnosis (microbiological and/or clinical), complications and therapy of infections. *Staphylococcus epidermidis* and *Staphylococcus aureus* were the microorganisms most frequently isolated. It was not possible to determine the incidence of infection associated with pacemakers, since the studies were generally of prevalence. In terms of therapy, the complete removal of pacemakers stood out, especially in cases of suspected biofilm. Still controversial is the use of systemic antibiotic prophylaxis in reducing the incidence of infection associated with implantation of a pacemaker.

Introduction

Cardiac pacing was introduced into clinical practice in the 50s with the primary objective of eliminating the symptoms and reducing mortality of patients with advanced atrioventricular blocks. Advances in pacemaker manufacturing and implantation technology, plus the electrophysiology knowledge of cardiac conduction disorders, enabled a consistent progress in cardiac pacing, extremely diverse in its mode of operation, with high physiological reliability and safety[1].

Although pacemaker implantation surgery is considered less complex, it is important to observe that, for being an invasive procedure and representing a foreign body, it puts the patient at risk for various complications, sometimes due to failures of generators, tissue damage or due to the implantation technique[2,3]. The diversity of techniques and conducts has provided improvement in surgical technique, however, there is limited information on the implications and effects of these improvements[4].

One concern among professionals is the risk of biofilm formation and, consequently, infection. In recent decades, biofilms have been widely blamed for nosocomial infections, especially in prosthetic implants, tubes, probes and catheters[5-7]. It is speculated that the presence of pacemakers is conducive to microbial colonization, contributing greatly to the development of biofilm, which could explain the occurrence of endocarditis[6-10].

It is worth noting that the biofilm consists of a structured community of microbial cells adhered to a solid surface surrounded by a matrix of extracellular polymeric substances. This microbial association is a form of protection against its development, encouraging symbiotic relationships and tolerance to antimicrobials. The literature on biofilm as a risk factor for health progressed from the 90s[5]. The biofilm formation involves a sequence of events, such as the initial reversible adherence of microorganisms to the surface of the solid substrate, microbial growth, matrix production of extracellular polymeric substances and detachment of sessile cells, which in planktonic form may cause infection or biofilm formation in other locations.

In biofilms, microcolonies are heterogeneous, consisting of microbial cells of one (monomicrobial) or more species (polymicrobial), functionally organized, where the organisms are protected from the action of macrophages and antibiotics. Moreover, the biofilm is roughly composed of 10 to 25% microorganisms, and 75 to 90% extracellular polymeric substances[11].

One concern among scholars is the infection that the biofilm triggers, and in many cases of implants, device replacement is the alternative indicated[11]. Accordingly, it is worth noting that it is crucial to investigate the biofilm when there is persistence of infection[12].

Particularly, the implantation of pacemakers is a procedure characterized by a low complication rate, however, infections, mainly that of pacemaker generator pocket is one of the most common complications with incidences ranging from 1-5%[3-17]. Despite the low

Keywords

Pacemaker, artificial/trends; biofilms; prosthesis-related infections.

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incidence, such infections have a worrying development mostly often with high morbidity and potentially fatal.

Several conducts have been described for the treatment of infection of pacemaker pocket. More conservative therapeutic approaches seem to produce higher rates of relapse or failure of treatment[2-18], and the best results relate to more aggressive approaches, with complete removal and implantation of new endocardial systems[3-8], which is usually associated with high hospitalization rates and high costs[3].

Given the above, this study aimed to describe the scientific evidence about the biofilm formation and occurrence of infection associated with pacemakers in order to identify key recommendations for the prevention and control. It also aims to evaluate in the studies the incidence of infection and the microbial flora in pacemakers. Evidence-Based Practice was the theoretical reference which, in a medical problem, allows evaluating critically the production of scientific knowledge to support the decision[19].

Methods

The method used was an integrative literature review, which is part of the Evidence-Based Practice, which allows the synthesis of evidence available on a defined issue, contributing to the deepening of knowledge on the subject investigated[19].

The articles select was based on the following question: *What has been published on biofilm formation and infection related to cardiac pacemakers?*

To search for articles, we used the data bases Medical Literature Analysis and Retrieval System (MEDLINE), Latin American and Caribbean Center on Health Sciences (LILACS), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library, with Internet access. The descriptors were biofilms, pacemaker, artificial cardiac and infection, selected from the definitions in the Medical Subject Headings (MESH) and Descriptors in Health Sciences (DeCS) from the Virtual Library on Health (BVS).

The studies selected were classified according to level of evidence: 01) systematic review or meta-analysis of randomized controlled trials; 02) at least one well-designed randomized controlled clinical trial; 03) well-designed clinical trials without randomization; 04) from well-designed cohort and case-controls; 05) systematic review of qualitative and descriptive studies; 06) single descriptive or qualitative study; and 07) opinion of authorities or reports of specialist committees[20].

The publications on the subject collected in full, in Portuguese, English and Spanish were included. The following exclusion criteria were established: structured studies in animal models and those related exclusively to the technique of implantation of pacemaker. Thus, through the careful reading of the title and abstract of the article in order to check consistency with the guiding question, 14 publications were collected, 05 in MEDLINE, two in LILACS, 05 in CINAHL and three in Cochrane Library. Two articles were found in two databases.

Results and discussion

We have found 14 publications since 1984, of which 06 were conducted in the USA, two in Spain, and only one in Austria, one in Brazil, one in Canada, one in Finland, one in France and one in Sweden. Accordingly, 12 were in English, one in Portuguese and one in Spanish. Box 1 shows the different designs of the studies and the levels of evidence. Thus, no systematic review study or meta-analysis of randomized controlled trials was evident, only two (14.3%) with level of evidence 02, 08 (57.1%) at level 04 (well-designed cohort and case-control) and 04 (28.6%) with levels 06 and 07.

Box 2 presented a synopsis of publications concerning the infections resulting from implants of pacemakers. It shows that the focus of attention of researchers permeated aspects related to microbiology, clinics, complications and treatment. Especially on the subject of biofilm in pacemakers, there were only two (14.3%) studies. It is speculated that the occurrence of biofilm formation is inevitable, but its confirmation in pacemakers involves removal of the implanted device, as well as advanced technology for scanning electron microscopy.

With regard to aspects of microbial etiology, there was a concern focused on species and susceptibility profile or multidrug resistance of strains to antibiotics. The emphasis is on the appropriateness of antimicrobial therapy. Out of the total, only two (14.3%) studies were clinical trials of prophylactic antibiotics. This topic is still controversial among surgeons and infectious disease physicians, whether in the prophylaxis and/or therapy.

It is noteworthy that the findings from this research do not determine the real situation of occurrence of infection associated with pacemakers, since the studies relate to a few situations. In this sense, data on the occurrence of biofilms in pacemakers are scarce, considering that this is a complex injury that is difficult to diagnose. Besides this, the population likely to use this device, in general, are the elderly with a history of arrhythmias, older age groups, and therefore with greater likelihood of infectious complications. Another aspect that makes it difficult to report the disease is that the appearance of symptoms of infection may be late, often not associated nor treated as a biofilm.

However, the incidence of infections related to cardiac devices has been reported between 0.5% and 12%. In recent publications, the incidence is smaller than 5%[8] or close to 7[21]. Endocarditis associated with pacemaker lead is rare, but it is considered a serious infection. It was estimated that the incidence of endocarditis is 19.9%, however, this rate has probably been overestimated due to the absence of stringent criteria for diagnosis. Endocarditis associated with pacemaker lead was described in 16 patients in the transvenous removal group and 11 in the cardiopulmonary bypass group[10].

In the United States, each year about one million cases of nosocomial infections are associated with devices and about two thirds are caused by Staphylococcus aureus or Staphylococcus epidermidis[12]. Although approximately 1%

of patients with endocardial pacemakers developed sepsis[22]. Infections associated with pacemakers are usually caused by *S. epidermidis* or *S. aureus*[4,9,12,24,26,27], and there was only one case of infection with *Aspergillus spp*[23]. Greenspon et al[9] showed that *S. aureus* was the most common cause of endocarditis associated with pacemaker (53%), followed by *S. epidermidis* (22%) and streptococci (12%). Early infections occurred within 06 months and late infections in about 32 months. They also noted that the skin flora is the probable origin of endocarditis associated with pacemaker lead[9]. These data leads us to the studies on biofilm formation that justifies the prolonged time to the onset of the first symptoms of infection.

In another study, *S. epidermidis* was the microorganism that caused most infections related to pacemakers[24]. The infection may involve any part of the pacemaker: the pocket, leads and the area of implantation of leads in the endocardium[21]. Moreover, biofilm formation by *S. epidermidis* may be influenced by the metal surface[18].

Infections associated with surgical implants are generally more difficult to treat because they require a long period of antibiotic therapy and repeated surgical procedures, with dramatic clinical and economic consequences. Mortality is higher among patients with cardiovascular implants and the cost of the device is a small fraction compared to the amount for the treatment of implant-related infection. The most important clinical goals in the treatment of these infections are to treat the infection, prevent recurrence, preserve function, set aside the risk of endocarditis and reduce the risk of death. Most often, these goals can be achieved by antimicrobial therapy and surgical intervention. And, perhaps, manufacturing and using cardiac pacemakers impregnated with antimicrobial agents. The diagnosis of infection from implant requires the presence of clinical manifestations and pathogens in surgical specimens, and blood cultures may be negative in cases of infection related to pacemakers, except in endocarditis associated[12].

A study of different treatment modalities of 38 patients with cardiac device-related infection, had 12 patients treated only with antibiotics, 19 had the device removed, reimplantation followed by antibiotics for short periods

Box 1 - Distribution of publications on biofilm in pacemaker according to year, title, study design, level of evidence and category

Year	Title	Design	Level of Evidence	Category	Reference
1984	Morphology of bacterial attachment to cardiac pacemaker leads and power packs.	Laboratory experiment	Level 4	Diagnosis (microbiological)	25
1985	Disseminated aspergillosis and pacemaker endocarditis.	Case Report	Level 7	Diagnosis (microbiological)	22
1986	Prevención y manejo del marcapaso infectado.	Prospective longitudinal	Level 4	Therapeutic	2
1986	Antibiotic prophylaxis in pacemaker surgery: a prospective double blind trial with systemic administration of antibiotic versus placebo at implantation of cardiac pacemakers.	Randomized Double-Mask Clinical Trial	Level 2	Therapeutic	4
1994	Antibiotic prophylaxis in permanent pacemaker implantation: a prospective randomised trial.	Randomized Clinical Trial	Level 2	Therapeutic	26
1995	Biofilms in device-related infections.	Review Study	Level 6	Diagnosis (microbiological)	6
1999	Complications related to permanent pacemaker therapy.	Retrospective	Level 4	Complications	24
2001	Técnica de implante subpeitoral para tratamento de infecção de loja de marca-passo: estudo inicial.	Prospective	Level 4	Therapeutic	3
2003	Involvement of adherence and adhesion Staphylococcus epidermidis genes in pacemaker lead-associated infections.	Laboratory experiment	Level 4	Diagnosis (microbiological)	23
2003	Antimicrobial strategies for the prevention and treatment of cardiovascular infections.	Review Study	Level 6	Therapeutic	20
2003	Surgical treatment of pacemaker and defibrillator lead endocarditis: the impact of electrode lead extraction on outcome.	Prospective section	Level 4	Diagnosis (clinical and microbiological) and Therapeutic	8
2004	Treatment of infections associated with surgical implants.	Review Study	Level 6	Diagnosis (clinical and microbiological) and Therapeutic	12
2006	Transvenous pacemaker lead removal is safe and effective even in large vegetations: an analysis of 53 cases of pacemaker lead endocarditis.	Retrospective observational	Level 4	Diagnosis (clinical and microbiological)	10
2008	Lead-associated endocarditis: the important role of methicillin-resistant Staphylococcus aureus.	Retrospective observational	Level 4	Diagnosis (clinical and microbiological)	9

(10-14 days) and 07 patients received a longer period of 06 weeks of antimicrobial agent. The first group had recurrence of infection and in the other two, patients had the infection completely solved. This demonstrates the importance of removing the device in the treatment of infections[21].

According to Darouiche[12], most implants contaminated with *S. aureus* or *Candida* spp. require surgical removal. The author justifies that it should be fully removed even if the contamination is only in the pacemaker pocket, because other parts of the device may also be contaminated. In the patients who respond to drug therapy, the implant should not be removed. Although removal of the implant is associated with the solution of the infection, it has to be authorized in patients at risk for complications during surgery and post-surgery[12].

As mentioned, treatment of infection associated with the system of artificial cardiac pacemaker is diverse. In cases with systemic sepsis or endocarditis, there is still a tendency to more aggressive approaches with prolonged intravenous antibiotic therapy (04 - 12 weeks), removal and complete replacement of endocardial systems.

The result of the microbial culture is another aspect that defines the therapy, that is, conservative approach in cases of *S. epidermidis* or aggressive intervention for *S. aureus* have been recommended. Thus, we use the antibiotic therapy associated with the repositioning of the generator or the complete removal of endocardial systems and implantation of a new one, antibiotic therapy associated with local measures and irrigation, among others. All of these are coordinated with long periods of hospitalization, high costs and controversial results. The subpectoral implantation technique proved to be a feasible alternative in the treatment of pacemaker generator pocket infection, showing 100% effectiveness, a shorter hospital stay and a lower cost. However, further studies and follow-up are necessary for a definitive conclusion[3-12].

Scholars have shown that the synergy of different combinations of antibiotics against biofilms of *S. epidermidis* varied with the time of biofilm formation (06, 24, 48 hours). In general, all combinations of antibiotics were effective in new biofilms. The combination of vancomycin and rifampin had a bactericidal effect in 06 hours, and in old biofilms, the combinations with tetracycline were more effective. The difficulty of eradicating older biofilms was evident[21,23].

There are genes of biofilm formation mediation, such as genes of attachment (fbe and atlE) and adhesion (ica), which were observed in most strains of isolated *S. epidermidis* of patients with pacemaker. These data indicate an important role of adhesion genes in infections in pacemakers[24].

In the study by Marrie et al[22], scanning electron microscopy revealed a different colonization in the pacemaker lead and the microorganism *S. aureus* was isolated at several sites. An extensive biofilm on the inner surface of the lead was then exposed and the external surface had a huge mass of biofilm with a population of bacterial cells adhered. All areas with cracks accumulated biofilm, which may justify the difficulty of action of therapy with antibiotics[22]. Therefore, in most cases, the removal of endocardial systems is indicated[2-10,12,22].

In a controversial manner, Bluhm et al[4] state that the use of a modern surgical technique combined with a meticulous aseptic practice excludes the use of systemic antibiotic prophylaxis in the implantation of pacemaker.

There are reasons to expect that the development of pacemaker technologies has an impact on reducing rates of complications. Aspects such as the reduced size of the generator, increased quality and durability of leads, improved implantation techniques and aseptic procedures. However, dual-chamber stimulators, with the introduction of two leads, result in a longer implantation time, increasing the rate of complications. In 27-month follow-up after implantation, approximately 14% of patients had a complication. In most cases, complications from a clinical standpoint were low and with no deaths. In this study, infection rates were similar in patients receiving antibiotics (1.2%) and those who did not (1.7%), but there was no randomization of participants in the groups[25]. The benefit of administering antibiotics to reduce the risk of infection is still controversial.

It is still worth noting the following facts:

- The formation of extracellular polysaccharide by *S. epidermidis* was significantly higher in pacemakers than in intravenous catheters, which makes the threat by biofilm even higher[26].
- The difficulties inherent in the safety of reprocessing devices also represents a high risk of contamination. There are reports of reprocessing of pacemakers that were removed from patients with infection[2].
- Antibiotic prophylaxis, although controversial, seems to be promising in the prevention of infectious complications after pacemaker implantation[8,10,27].
- In terms of sensitivity profile, researchers found that 67% of infections were associated with *S. aureus* resistant to methicillin, suggesting that this is an important pathogen of endocarditis associated with pacemaker lead[9].
- A new technique for the management of pacemaker pocket infection without the removal of endocardial systems proved, in principle, a feasible low-cost alternative, however, we still need follow-up studies for a definitive conclusion[3]. This was the only study that proposed an alternative for the treatment of infection related to the pacemaker and has had good results.
- From complications related to pacemakers, 6.7% were early and 7.2% were late, and 3.1% related to implantation[25]. In the study by Maduro Maytin et al[2], pacemaker pocket infection was a complication related to late re-interventions (0.4%).
- Regarding the biofilm, adhesion genes were almost always present in species recovered from patients with pacemakers, indicating the important role of these genes in the pathogenic mechanisms of pacemaker-related infection[24]. Differences in biofilm morphology may reflect the degree to which

the fibrin and other materials become embedded in the developing biofilm[26]. The age of the biofilm may interfere with the action of antibiotics, because they are more effective in younger biofilms. They also predict that the resistance of microorganisms to antibiotics will make the treatment of cardiovascular infections harder[21].

Systemic antibiotic prophylaxis significantly reduces the incidence of infectious complications after implantation of a permanent pacemaker[8,10,27]. In another study, there was no recurrence of infection after removal of the pacemaker lead; this is an effective procedure that can be applied even in patients with biofilms larger than one centimeter. Therefore, in pacemakers with biofilms larger than two centimeters in diameter, the recommendation was removal[10]. Maduro Maytin et al[2] performed antibiotic prophylaxis within 24 hours before the implantation of a pacemaker and 05 days after, with a total of 0.4% of late infections in reoperations. In particular, researchers found that infections occurred in patients who did not receive antibiotic prophylaxis[27]. That said, there is strong evidence that the best approach for eradication of infection associated with biomaterial implants and reduction in mortality is the surgical intervention[2-10,12,26]. It seems consensus that all endocardial systems should be completely removed to eradicate infection from biofilm formation.

Conclusion

The biofilm is a current and little studied topic in the field of cardiology and even less when connected to the pacemaker. The conditions concerning the nature of the

Box 2 - Synopsis of publications related to biological risk and formation of biofilm in cardiac pacemakers according to the study objective, main results and conclusions

Ref.	Objective	Results	Conclusions
25	To examine three patients with infection in the pacemaker pocket.	The patients had the pacemaker pocket infection caused by *S. epidermidis*. The internal surfaces were less colonized and the leads also showed biofilm.	Differences in biofilm morphology may reflect the microbial nature as a way of accession.
22	To report a case of disseminated infection and endocarditis associated with permanent transvenous pacemaker.	65-year-old woman with fever of unknown origin, generalized aspergillosis with endocarditis. There were no known risk factors for the development of fungal infection.	Aspergillosis is rare and there is difficulty in diagnosing it. Sepsis and endocarditis are well-defined complications of heart rate and should be considered in the differential diagnosis of infection.
2	To address prevention and control of infection associated with infected pacemaker.	There were 182 complications in primary implants and 44 in reoperations. The total number of infectious complications was 3.09% and 0.4% respectively. In contaminations, the stimulation unit was removed, medical treatment, reimplantation and in most cases, the endocardial systems were completely withdrawn.	It was concluded that success is a complex task that involves staff, provision of improved techniques and advances in biomaterials.
4	To evaluate antibiotic prophylaxis in the implantation of pacemakers.	Infection of the pacemaker was not diagnosed in any patient in either group.	This study suggests that antibiotic prophylaxis does not need to be routinely performed to implant artificial pacemakers.
26	To determine whether antibiotic prophylaxis is effective in patients who underwent implantation of a pacemaker and to identify major risk factors for infection.	There were 13 infections, 12 in the group without antibiotic. Nine of the infections were presented as erosion of pulse generator or lead, three as sepsis secondary to S. aureus and one with an abscess of pocket secondary to S. epidermidis. Infection was more common when the surgeon was inexperienced, when the procedure was extended, or after a repeat operation for complications.	Antibiotic prophylaxis significantly reduces the incidence of infectious complications that require a repeat operation after implantation of a permanent pacemaker. It is suggested that antibiotics should be used routinely.
6	Assess publications related to the development of biofilm on medical devices.	Several devices are considered at high risk of biofilm formation and thus responsible for infection.	Biofilm formation is related to the host, biomaterial nature and the microorganism. Emphasizes the importance of developing biomaterials that resist the initial accession.
24	To evaluate complications related to permanent implant of pacemakers.	Pacemaker infection was detected in 1.8% of patients. Early complications were detected in 6.7% of patients, of whom 4.9% required invasive treatment. In 7.2%, there were late complications, and 3.3% needed reoperation. There were no deaths.	Most complications occurred in the first three months after implantation. Complications associated with pacemakers are uncommon.
3	To demonstrate an alternative for the management of infection of pacemaker pocket.	There were no deaths and cases of reinfection, the mean hospital stay was 7.3 days and the antibiotic therapy was 7.0 days. There was no need for rapprochement.	At first, the new technique proved to be a feasible alternative in the treatment of pacemaker pocket with high efficiency and low morbidity.

Continuation

Ref.	Objective	Results	Conclusions
23	To compare S. epidermidis of patients with infections related to pacemaker and infections through intravascular catheter.	Adhesion genes were present in species recovered from patients with infections related to pacemaker and intravascular catheter infections.	The data reported indicate an important role of adhesion genes in pathogenic mechanisms related to pacemakers.
20	To investigate current and new treatments for resistant microorganisms in cardiovascular infections.	New antimicrobial agents were introduced against the resistance of Gram-positive organisms, which are responsible for cardiovascular infection. The study demonstrates the importance of removing cardiac devices to treat these infections and the effectiveness of combinations of antibiotics varies with the age of the biofilm, being more effective in younger biofilms.	The progressive increase of resistance of microorganisms to antibiotics will make the treatment of cardiovascular infections even harder in the near future. Strategies that include combinations of antibiotics and attack to biofilms with new agents are points for exploration in the future.
8	To evaluate the clinical and echocardiographic characteristics of patients with pacemakers or cardioverter-defibrillator and relate the treatment with microbiological variables.	Out of 669 patients with pacemakers, 31 had infective endocarditis. The most frequently isolated microorganism was S. epidermidis. Non-removal of the pacemaker was first performed in 7 patients; all of them had recurrence of endocarditis and died. The other patients underwent surgical removal, one patient relapsed, three died after surgical treatment and the others were treated successfully.	It is concluded that the extraction of the pacemaker should be considered for most patients with cardiac device-related endocarditis.
12	To investigate infections associated with implants, to describe the clinical effects and challenges in diagnosis and treatment.	The treatment of infection may be through antibiotic or surgical intervention. One possible reason for the reduced susceptibility of microorganisms to be incorporated into the biofilm are the antimicrobial agents that promote a slower bacteria growth rate in the biofilm, inhibition of antimicrobial activity and reduced penetration of the biofilm. Most implants contaminated with *S. aureus* or Candida spp. require surgical removal.	Recurrence of infection is generally more likely in patients treated with antibiotics or with antibiotics plus removal of the generator only, than in those undergoing removal of all endocardial systems. In the patients who respond to drug therapy, the implant should not be removed.
10	To describe the clinical and microbiological conditions of patients with endocarditis induced by the pacemaker lead and to assess the biofilm formation.	Complications associated with pacemaker pocket and endocarditis caused by the pacemaker lead were observed in 16 patients in the transvenous removal group group and 11 in the cardiopulmonary bypass group. Perioperative mortality was 5.7%, all were subjected to removal and had endocarditis in the tricuspid valve. There were no deaths among those who underwent transvenous removal of biofilms with masses greater than one centimeter.	This study demonstrated that the transvenous removal of pacemaker lead is a safe and highly effective procedure in cases of infected pacemakers.
9	To analyze the cases of endocarditis associated with pacemaker lead and evaluate the clinical and microbiological picture.	Nineteen infections occurred within 06 months. The remaining 32 infections occurred 06 months later. Thirty-three patients had pacemakers and 18 implantable cardioverter-defibrillator. The most frequently isolated microorganism was S. aureus, followed by S. epidermidis (22%) and streptococcus (12%). *S. aureus* resistant to methicillin affected 67% of infections. S. epidermidis was responsible for 26% of onsets and 19% of late cases. All devices were removed.	Suggest that methicillin-resistant *S. aureus* is an important pathogen for infective endocarditis associated with pacemaker lead. These data suggest that strategies to prevent hematogenous infection, particularly with *S. aureus*, are critical in patients with implantable cardiac devices.

biomaterial, added to factors of risks to patients, such as extremes of age, immunocompromise due to multiple causes, underlying diseases, characterize the profile of the situation that deserves attention. In particular, additional research is needed to determine the current status of complications from the use of pacemakers in different patient populations, because studies examined individually signaled no statistically significant differences in the rates of infection.

On the other hand, no study has explored the nature of biomaterials that compose the pacemakers and biofilm formation. Thus, the question is: will pacemakers impregnated with antimicrobial agents reduce or inhibit biofilm formation?

In summary, the data analyzed show that the topic is of great importance and has been little studied, since in 24 years only 14 articles were published. With regard to professional nursing, even if it plays a key role in direct and/or indirect assistance to patients subject to the use of a pacemaker, both in implantation and in follow-up, especially in detecting signs and symptoms of infection, their participation was zero in these studies. Given the risk

of infection associated with invasive procedures, it is worth noting the value of preventive measures.

It also makes us think about the importance of measures of surveillance of infections, mainly in Brazil, a country marked by cultural diversity, socioeconomic inequalities, heterogeneous patterns of health care in terms of physical structure, type of patients and infections. Besides that, the Brazilian health system has historically faced the serious problem of social expansion, which is combined to a lack of human resources and inappropriate technology. Undoubtedly, these are fertile conditions for rising infection rates.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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