Management of cardiac device infections according to current data

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Abstract

The use of implantable devices in management of cardiac diseases is increasing as a result of improvements in technology of permanent pacemaker and implantable cardioverter defibrillators. Device related infections are also rising accordingly and have become an important clinical problem. Accurate diagnosis and optimal management of these infections is challenging, necessitating complete removal of the device and prolonged antibiotic therapy. In this regard, a multidisciplinary approach is required with the essential support of microbiology and imaging modalities. This paper highlights the current literature on the pathogenesis, risk factors, diagnosis and management of device related infections *(Anadolu Kardiyol Derg 2014; 14: 76-81)*

Key words: cardiac device infections, device related endocarditis, implantable cardioverter defibrillator, permanent pacemaker

Introduction

In recent years, around the whole world, permanent pacemakers (PPM) and implantable cardioverter defibrillators (ICD) implantations have been progressively rising. This increase can be attributed to widened indications of resynchronization and defibrillator devices (1). Device related complications are also rising accordingly. Infection is the major complication of the device implantation procedure. Device infections are related with morbidity and mortality rates, and require aggressive management (2). In the United States of America, between the years of 1993 and 2008, the increase in cardiac device infections was detected as high as 210%, while the incidence of device related infections was 1.61% at the same period (3). As device related infections are becoming more common, the physicians should be aware of this complication in order to prevent and treat it properly. This paper summarizes the current algorithms and the management of device related infections according to recent guidelines.

Clinical presentation of the device related infections and classification

PPM and ICD related infections can be classified into four groups; namely, local pocket infections, cardiac device related infective endocarditis (CDRIE), bacteremia with pocket infection and resistant bacteremia without any identifiable focus. The most frequent presentation is local pocket infection. The signs and symptoms of the pocket infections can be local pain, swelling, redness, ulceration and erosion of the skin. In a recent study, it has been revealed that the percentage of the admission with the local signs of pocket infection was 70% (2). In another study, out of 189 patients with device infection who were referred for lead extraction, 69% had local signs of pocket infection (4). The infection generally arises during implantation as a result of device contamination. At later stages, ulceration of the adjacent skin and contamination by local flora, can cause infection. CDRIE is more prevalent on tricuspid valve and generally causes valvular regurgitation. Greenspon et al. (5) classified CDRIE as early (first 6 months) and late CDRIE (after 6 months of the implantation). Local pocket infection signs were found in 54% of the patients with early CDRIE. Patients with late CDRIE had more frequent systemic signs such as having fever, chills and sepsis. There was a distant focus like central catheters, arteriovenous fistula, osteomyelitis or a localized abscess in 38% of the patients presented with late CDRIE (5).

Predisposing risk factors for device related infections

Patient, device, procedure and operator related factors can all be responsible for device infection. Patient related predis-

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posing factors are chronic renal failure, hemodialysis, diabetes mellitus, cirrhosis, anemia, chronic lung disease, active infection, fever preceding device implantation, oral anticoagulation, long standing steroid use, permanent central catheters, prolonged or recurrent hospitalization (3, 5-8). Increased age and male gender are other factors for device infection (9). Device related factors include device size, multiple electrodes, uneven surface of the device and the convenience of the device for bacterial adherence (7, 10, 11). Using temporary pacemaker, implantation of generator to the abdominal region, formation of hematoma after implantation, reimplantation of the device, revision after the procedure, breaking sterilization rules around the surgical theatre, and using povidone iodine for surface antiseption are well known procedural factors (6, 8, 12). The main operator related factor is the experience of the operator (11). The higher volume capacity centers have less cardiac device infection rates compared to those of lower volume centers (8, 13).

Etiology and pathogenesis

Cardiac device infections can occur by contamination during implantation or by contamination with local flora after erosion of the skin by the device generator. Occasionally, hematogenous dissemination from a distant focus may induce device related infection. Immune system of the host, microorganism and device type are also playing a part (11).

Device infections are common after gram (+) cocci bacteremia (especially *S. aureus*) (14). During *S. aureus* bacteremia, device infection rate is 55%; while the rate is 30% during bacteremia of other gram (+) cocci species (15, 16). Device related infections are uncommon during gram (-) bacteremia (17). Staphylococci species are the major agents causing cardiac device related infections with the rate of 70-80% (2, 4, 18). Borgiorni et al. (18) isolated gram (+) bacteria at a rate of 92.5%. Of all, coagulase negative staphylococcus (CNS) was the major pathogen (69%). *S. epidermidis* (67%) was the most prevalent microorganism among CNS. CNS generally exhibits less pathogenic properties while *S. lugdunensis* has a quite aggressive course (18). CNS usually colonizes over the skin and produces various adhesion molecules to adhere prosthetic materials. They have a biofilm that protects them from the antibiotics and immune system of the host (19). Other pathogens are *corynebacteria, propionibacterium acnes, peptococci, pseudomonas aeruginosa, enterobacter*, *candida and aspergillus* (7).

Diagnostic tools to detect device infections

Microbiology

Blood cultures should be withdrawn to detect accompanying bacteremia before antiobiotherapy is commenced. Microbiological parameters, clinical findings and imaging modalities should be utilized to confirm the diagnosis in case of isolation an atypical microorganism for CDRIE. Isolation of typical pathogens (*S. aureus*, *viridans streptococci and enterococci*) in one blood culture can indicate CDRIE (20). In case of negative blood cultures, definite etiology requires microbiological evaluation of the extracted device and electrodes.

Percutaneous aspiration of the device pocket is not recommended in patients presenting with local signs of pocket infection (11). After removing generator and electrodes, all system should be sent for microbiological evaluation. Each electrode's base and tip should be evaluated separately for culture. Obtaining tissue sample provides more accurate microbiological diagnosis compared to getting swabs from the device pocket (21, 22). In cases other than infection, routine microbiological evaluation is not recommended after extraction procedure (11). After extraction of the device without an accompanying infection, routine microbiological investigation showed one positive culture out of three swabs (23). Those positive results may arise from both contamination and colonization, either of them is not a definite risk factor for device related infection (23).

Transthoracic (TTE)/transesophageal echocardiography (TEE)

Echocardiography should be performed to all patients with local pocket infection signs and to the patients who have a suspected device related infection (24). TEE is more sensitive than TTE in detecting lead vegetation. TEE is recommended as first line diagnostic tool for bacteremia with *S. aureus* on behalf of increased device related infection risk in those patients (25). Even when vegetation is displayed by TTE, TEE is still recommended to explore the adjacent cardiac structures, to evaluate valvular involvement and to measure vegetation size (class I indication) (11). TEE is recommended when blood cultures are positive and when there is a history of antiobiotic use before admission in case of negative blood cultures (class I indication) (11). TTE can also be used to evaluate right heart dimensions, pericardial effusion, and left ventricular function. It is not always feasible to identify an oscillating mass over the electrodes by using echocardiography. Blood culture and inflammatory status should be carried out in asymptomatic patients when a mass identified during a random evaluation. In case of negative blood cultures and normal inflammatory status, an outpatient TTE follow-up should be the management modality in addition to anticoagulation. Antibiotic therapy or lead extraction is not recommended. In a retrospective study, 5% of the masses over electrodes were thrombi (25). TEE does not definitely exclude cardiac device infection; hence, several imaging modalities are currently being investigated in that era.

Novel imaging techniques

Positron emission tomography (PET), three dimensional echocardiography, intracardiac echocardiography, cardiac computed tomography, radionuclide scan are promising imaging modalities to diagnose uncertain cases.

Comparing to TEE, intracardiac echocardiography was found to be superior in measuring vegetation size. It also gives the advantage of safe tool utilization during the extraction proce-

dure (26). There has been limited data about the radionuclide scanning in detecting device related infection. Gallium 67, indium 111 leukocyte or technetium 99 leukocyte imaging modalities are successful in revealing device pocket infection, and subcutaneous or intravascular electrode involvement (27-29). F-18 fluorodeoxyglucose (F-18 FDG) PET scan is a beneficial tool to detect the location of the infection (30, 31). In a study, the sensitivity and specifity of the F-18 FDG PET were 100% in detecting device related infection (31). In the same study, the sensitivity and specifity of PET for electrode involvement were 60% and 100% respectively (31). However, in a study of Ploux et al. (30) PET's sensitivity and specifity in detecting cardiac device infection was 88% and 85% respectively. When there is a suspicion of cardiac device infection, presence of ambiguity about the dissemination of the infection, and presence of fever or bacteremia of unknown origin, PET can be useful (30). Higher cost radiation and unattainability limit its extensive utilization.

Management

Medical treatment

Conservative therapy alone is not sufficient to treat the device related infections. Following the diagnosis, whole system should be removed as soon as possible. After taking blood samples for culture, empirical antibiotic therapy should be commenced according to the local center's resistance protocols. It should be emphasized that staphylococcus, the most prevalent pathogen, has methicillin resistance at a rate of 30% (18). Vancomycin should be considered for those species. Culture results and antibiotic sensitivity profile should lead to final treatment. The impact of the medical treatment can be assessed by demonstrating negative blood cultures, resolving fever and regression of the inflammatory markers. The duration of the antibiotic treatment should be 10-14 days in patients with isolated pocket infection (class I indication). In patients with hematogeneous dissemination, antibiotic treatment should be continued at least 14 days following device extraction (class I indication). The antibiotic treatment duration should be extended to 4-6 weeks in complicated cases (CDRIE, osteomyelitis, septic trombophlebitis or persistent positive blood cultures after device removal) (class I indication). When device cannot be removed because of the comorbidities, suppression by prolonged antibiotic treatment may be considered (class IIb indication) (11). In a recent study by Lopez et al. (32) a closed antimicrobial irrigation system was used successfully to treat pacemaker infection in five patients who had comorbidities or access site problems for extraction procedure.

Interventional/surgical treatment

Infection is the most common indication for electrode extraction. Percutaneous procedures should be performed for device removal; however, in case of failure, patients should be referred to surgery. If the device is not removed after an infection; mortality, morbidity and recurrences significantly increase (4). Manually traction is the first preferred method for percutaneous procedure. In case of failure, specially designed tools for extraction such as; polypropylene/polytetrafluoroethylene dilator sheaths, laser sheaths, mechanical dilator sheaths or electrosurgical dissection sheaths should be used. PLEXES study proved that laser sheaths can be used successfully for electrode extraction. In that study, complete lead removal rate was 94% in the laser group and 64% in the non-laser group, the major complication rates were similar (33). In a recent study, the success rate of mechanical dilator sheaths for lead extraction was 93% (34). Although those rates are encouraging, successful lead extraction requires a learning curve. The Expert Consensus, published in 2009 by Heart Rhythm Society, recommends utilization of the lead extraction procedure by experienced operators due to likelihood of life threatening complications during the operation (21). Myocardial perforation, right atrial laceration and vein damages are examples of the procedure related fatal complications (35, 36). During the lead extraction procedure, a cardiovascular surgery team should be ready for an emergent surgical back up. The type and location of the electrode, advanced age, female gender, implantation time of the electrode, calcification around the electrode and the experience of the operator are the predisposing factors for increased complication risk (37). The initial venous vein used for electrode implantation, is the preferred route for extraction. Alternative venous accesses may be used when the initial vein is not suitable for extraction or when there are accompanying lead fractures (38). The patient's clinical condition, another indication for cardiac surgery, pacemaker dependence, the need for simultaneous electrode implantation, the experience and the choice of the operator are the main factors for deciding the type of the extraction procedure. There is no consensus about the vegetation size for referral to surgery. For those vegetations larger than 20 mm the management should be decided in an individual basis according to clinical status, the experience and choice of the operator (11). Klug et al. (39) showed the success of the percutaneous extraction procedure in a group of patient that had large vegetations. Non-fatal pulmonary embolism was detected at a rate of 40% in those patients (39). Leads with vegetations larger than 20 mm were extracted successfully in experienced centers by percutaneous procedures (4, 38, 40, 41). Optimum timing for lead extraction remains controversial. In a study, in patients presented with local pocket infection, bacteremia or CDRIE, delayed procedures increased mortality whereas early extraction was related with better survival rates and shorter hospital stay (42).

The bacteremia of unknown origin in patients with devices is another challenging issue. Current guidelines recommend the extraction of the device and electrodes in patients with staphylococci bacteremia without a definite focus with class I indication,

while the extraction of the whole system is a class IIa indication for patients with resistant gram (-) bacteremia without a definite focus despite appropriate antibiotic management (11).

Timing for implantation of the new device

Following the extraction of the infected devices, patients must be evaluated carefully for the necessity of a pacemaker before implanting a new device (class I indication) (11). There is no definite agreement about the optimal waiting period for the new device implantation. In the light of recent guidelines; repeating blood cultures under antibiotic treatment is recommended after device removal. In patients with positive blood cultures and the vegetation is limited to electrodes, a new device implantation should be considered after obtaining negative blood cultures for 72 hours (class IIa) (11). When vegetation is detected on valvular structures, antibiotic treatment should be continued for at least 14 days after device removal, then new device implantation should be considered (class IIa) (11). When the device cannot be removed because of the comorbidities, suppression by prolonged antibiotic treatment may be considered (class IIb indication) (11). When there is septic thrombophlebitis on upper extremity veins where electrodes were implanted initially, anticoagulation therapy and delayed extraction until thrombus resolution may be considered due to increased risk of pulmonary embolism (43). The new device should be implanted to the contralateral venous system to prevent relapses. In pacemaker dependent patients, it is necessary to place a temporary lead, but this usually complicates the treatment of the infection. When there is need of cardiac surgery for another indication, the electrodes can be placed epicardially.

Prevention

Before device implantation, systemic infection should definitely be excluded. Preoperative antiseptic preparation of surgical site should be done accordingly. Routine antibiotic prophylaxis before device implantation is protective against device related infection (6, 7, 9). The recent scientific statement by AHA recommends appropriate antibiotic prophylaxis with an agent that has in vitro activity against Staphylococci (class I indication) (11). During the procedure, it is critically important to pay attention to sterile technique. Using a face mask is mandatory to cover operator's nose and mouth where staph species might colonize. Implanting the device beneath the muscle may prevent infection by providing adequate blood circulation especially when subcutaneous tissue is limited. Prevention of hematoma is also crucial, in case of hematoma, needle aspiration is not recommended as this may increase the risk of infection (11).

Currently there are no data to support the administration of postoperative antimicrobial therapy and it is not recommended because of the potential risk of adverse drug effects, the development of antimicrobial resistance and increased financial cost (44). Routine prophylaxis before invasive procedures (endoscopy, tooth extraction etc.) is not recommended in patients with cardiac devices (11).

Conclusion

The progressive increase in device implantation procedures has brought significant rise in device related infections. Early diagnosis, multidisciplinary approach and aggressive treatment are essential for optimal management to prevent serious complications. The clinical risk factors for pacemaker infection include renal insufficiency, active infection, diabetes mellitus, oral anticoagulation and corticosteroid use. The major pathogen is gram (+) cocci whereas uncommon agents may also cause infection. Echocardiography and microbiological evaluation of the blood samples, leads, and generator pocket tissue are essential parts of the diagnostic work-up. In complicated cases, the use of advanced imaging modalities should be considered. Complete removal of all system is strongly recommended as soon as possible after the accurate diagnosis of device infection, along with adjunctive antimicrobial therapy, unless the patient is at high risk for periprocedural complications due to accompanying comorbidities. In such cases, chronic suppressive antimicrobial treatment may be preferred. The interventional extraction procedures may cause life threatening complications and should be performed in experienced centers that can provide urgent surgical back up. When the percutaneous extraction procedure fails, surgical removal must be considered. After the extraction, patients must be evaluated for the necessity of a pacemaker. There is no definite optimal waiting period for the new device implantation, it should be decided after repeating blood cultures. Prevention is the most important issue to decrease the incidence of device related infections.

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