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Original Article

Pacemaker pocket infection due to environmental mycobacteria: Successful management of an outbreak and steps for prevention in future

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ABSTRACT

Background: An outbreak of surgical site infection (SSI) due to environmental mycobacteria (EMB) occurred in a hospital in Eastern India.
Method: A quality improvement project (QIP) was undertaken to analyze the causes and prevent further outbreak. Step (1) Proof of the need: Four patients who had undergone pacemaker implantation consecutively during a 10-day period developed SSI. Step (2) Diagnostic journey: Since all patients developed SSI within 2 months of implantation, a common source of infection was likely. Atypical mycobacteria (AMB) were grown from surgical sites as well as from the surface of operation table, image intensifier, and lead aprons. It was a rapid growing variety that lacked pigment, a characteristic of EMB with pathogenic potential. The EMB was finally traced to its source, the overhead water tank. Step (3) Remedial journey: By thorough cleaning of the water tank and enriching its chlorine content, the EMB was eliminated from its source. Step (4) Holding the gains: Protocol for cleaning the water tank once in 3 months was made. A checklist was prepared to ensure compliance to asepsis protocol in the operation theater. In the ensuing 5 years, the infection did not recur.
Result: The bacteria that caused SSI were identified as EMB that grew in the water tank and contaminated the operation room. It could be eliminated by appropriate measures.
Interpretation: Water is a potential reservoir for EMB. Use of the term 'environmental mycobacteria' instead of 'atypical mycobacteria' will generate awareness about contamination as the cause of SSI.

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1. Introduction

Surgical site infection (SSI) after permanent pacemaker implantation is very low (less than 2% of the annual implantations in most centers) and *Staphylococcus epidermidis* is the commonest pathogen.[1] We report an outbreak of pacemaker pocket infection due to environmental mycobacteria (EMB) and the corrective measures that were implemented.

2. Material

In our pacemaker implantation unit, the incidence of re-do surgery for deep SSI was 0.83% and occurred in 13 of the 1380 pacemakers implanted from 1982 to 2008.[2] They were sporadic and *S. epidermidis* was the culprit organism. But in the year 2009, of the 146 pacemaker implantation procedures, five procedures in four patients were complicated by SSI (3.42% of the annual implantations). Initial swabs from the infected sites neither showed any microorganism in Gram stain nor any bacterial growth on culture. Purulent discharge persisted despite antibiotics and microbiology tests were repeated. Acid fast bacilli were found on Ziehl-Nielson staining, which grew rapidly in Lowenstein-Jensen medium and were reported as 'atypical mycobacteria (AMB)'. The outbreak occurred in all four patients who underwent pacemaker implantation consecutively over a 10-day period from 21st March to 1st April 2009. The clinical presentation was that of SSI within 6 weeks of surgery with redness, purulent discharge, and non-healing operation site without any systemic feature like fever (Table 1). Only the 4th patient responded to antibiotics and wound dressing, while the rest required removal of the pacemakers, debridement, and reimplantation on the contralateral side after sterilization with ethylene oxide. The 2nd patient underwent reimplantation in the same operation theater (OT), before the bacteria were eliminated from their environmental source, which led to recurrent infection in the 2nd site as well. Thus, in four patients, there were five instances of SSI.

3. Method and results

The OT was closed in mid-June 2009 and a quality improvement project (QIP) was initiated. QIP is a tool to solve a problem through measures in cross-functional areas and is conducted in four steps.[3]

Table 1 – Profile of SSI due to EMB in four patients (AMB – atypical mycobacteria; EMB – environmental mycobacteria; QIP – quality improvement project; ATT – anti-tuberculous treatment).

#	Name Age & Sex	h/o DM Blood sugar < Sx	Date of primary Sx, Type of pacemaker, Peri-op antibiotics, Early course	Course of SSI, treatment and outcome
1	DC 52 years F	Non-DM 86 mg/dl	21st March 2009 Relia RESR01. Cefaperazone, Kloxacillin.	Abscess noted on 14th April 2009, 3 weeks after Sx. AMB in aspirated pus. ATT for 2 months – no response. Explanation and debridement on 26th June 2009. Wound healed well. A new Relia RESR01 was implanted in contra lateral side on 2nd August 2009 in the same OT. Healed well. Ok till March 2014
2	MMS 60 years M	DM 122 mg/dl	25th March 2009 Sigma SEDR01. Gentamycin, Kloxacilin. Healthy wound on Stitch removal.	Redness and discharge from 20th post-op day leading to sinus. Vancomycin > linezolid. Pus swab – no bacteria initially, then AMB isolated. ATT > Ofloxacin > Ciproflaxacin. Explantation and debridement on 1st June 2009. Re-implanted on the opposite site on 4th June 2009 in the same OT. Developed early SSI with persistent discharge, despite ATT, Ofloxacin > Trimethoprim/sulphamethoxazole. EMB suspected. QIP undertaken. Explantation and debridement on 7th August 2009. A new pacemaker, Adapta ADSR03 & lead were implanted on the first side on 14th August 2009 in the same OT. Healthy wound on stitch removal. Ok till March 2014
3	TA 53 years F	DM 211 mg/dl	27th March 2009 Adapta ADVDD01 Gentamycin, Kloxacillin.	Persistent slight ooze up to 29th April 2009. Pus swab sent – AMB isolated. Treated with linezolid, ciprofloxacin; alternate day cleaning and dressing. Satisfactory wound healing by end May 2009, followed for 2 months post-op. Ok till March 2014
4	RPB 75 years M	Non-DM 150 mg/dl	1st April 2009 Regency 2406L Cefaperazone, Kloxacillin. Healthy wound on Stitch removal.	Swelling at op site after 6 weeks > discharging sinus. AMB isolated from pus. ATT for 4 months-sinus persisted. Explanation and debridement on 14th November 2009. A new Regency 2406L was implanted on 25th November 2009. Healthy wound on stitch removal. Ok on follow-up till March 2014

Table 2 – Observation before the QIP and result/measures after the QIP.

Parameters	Observation before QIP	Results/measures after QIP
EMB in swabs from OT	Present	Absent
EMB in water tank	Present	Absent
Chlorine content of water	0.1–0.2 ppm	1.0 ppm (during the remedial journey)
Protocol for cleaning lead aprons	Absent	Weekly wash with soap and water
Cleaning of overhead water tank	Once a year	Once in 3 months
Cleaning of AHU filters	Weekly with water	Weekly with soap and water
Surveillance of OT asepsis	Not documented	Surveillance check list with assigned responsibility for compliance was incorporated as quality document
Microbiology test for mycobacteria in specimens from SSI	Not routinely done. Ziehl-Nielson stain was done in the cases in Table 1, since Gram stain was negative and no fungi were seen. Non-pigmented rapidly growing mycobacteria were seen on culture but antibiogram was not done	Ziehl-Neilson stain to be routinely done from SSI specimens. If acid-fast rods are detected, culture in Lowenstein-Jensen medium to be carried out. Antibiogram to be tested for the mycobacteria grown

Step 1: Proof of the need.

(i) SSI in four consecutive patients who underwent a pacemaker implantation consecutively over a 10-day period.

(ii) A rise in SSI rate from 0.83% (1983–2008) to 3.42% in 2009.

Step 2: Diagnostic journey and observations.

Root cause analysis: AMB isolated from the swabs taken from patients who underwent consecutive pacemaker implantations pointed to a common source for the bacteria.

A process flowchart of all the activities involved in pacemaker implantation was made. The method of sterilization of surgical instruments and surgical protocol in the OT were reviewed and found to be as per standard recommendations.[4] Swabs for microbiology testing were taken from the walls and floor of the OT, operation table, C-arm of the image intensifier, racks kept in the OT, lead aprons, lead collars, and surgical instruments. AMB was isolated from three objects – operation table, C-arm, and lead aprons. A commonality in the contaminated objects was searched by brainstorming and the source was thought to be water or dust. Tap water was used to wipe the operation table and C-arm before and after every procedure. Lead aprons that were worn before scrubbing tended to get splashed with water. There was no protocol to clean the lead aprons. The AMB grew within 3–5 days and lacked pigmentation, which is the characteristic of a group of EMB with pathogenic potential.[5] The group includes *Mycobacterium fortuitum* and *Mycobacterium chelonei/abscessus*, known to cause SSI.[6] Since the usual source of EMB is water and soil, we sent a sample of the tap water and took more swabs from floor, foot wear, and from the outlet of central air conditioning duct.[5] None of those samples grew mycobacteria, but it was isolated from a sample collected from the bottom of the overhead water tank. The next action was to find the reason for mycobacterial growth in the water tank. Chlorine content of the tap water was checked and found to be 0.1 ppm. At the source of water supply, chlorine was added @1 ppm, which was sufficient to prevent most of the water-borne diseases.

Step 3: Remedial journey and result. Municipal water stored in tanks could harbor EMB, since the chlorine content diminished progressively from source to end point.[7–9] For eradicating EMB, a higher concentration of chlorine is recommended.[4,10] The water tank was thoroughly cleaned and hypochlorite solution was added to initially achieve chlorine content of 2 ppm. Thereafter, a chlorine pump was installed for constant dosing from a container of hypochlorite solution, to maintain a concentration of 1 ppm.[4,10] Lead aprons and collars were thoroughly cleaned with soap and water. The OT table and C-arm were wiped clean with soap solution. A quality circle of the staff was formed to implement 5 S in the OT (sorting, shining, sweeping, systematizing, and self-discipline). Even though filters of the air-handling units were washed weekly with a forceful jet of water, washing with soap water was recommended as a general hygiene measure (Table 2). Effectiveness of the corrective measures was verified weekly, by checking for EMB in swabs and water samples. The density of EMB growth reduced, and after 4 weeks, none of the samples grew the organism. The OT became functional in early August 2009, after 6 weeks. None of the subsequent 56 pacemaker implantations in the year 2009 developed SSI

Table 3 – Surveillance checklist for maintaining asepsis in OT.

Activity	Frequency	Accountability
Cleaning of OT	Daily	Assigned staff nurse
Bleaching powder in wash areas, drains	Weekly – on Sundays	Assigned cleaning staff
Washing of lead aprons and collars	Weekly – on Fridays	Assigned staff nurse
Washing of OT	Weekly – on Sundays	Assigned cleaning staff
Swabs for microbiology test	Fortnightly	Sister in charge
Cleaning of filter at AC outlet	Weekly	Air conditioning staff
Cleaning AHU filters	Weekly	Air conditioning staff
Cleaning of water tank	Once in 3 months	Water management section
Super chlorination	Once in 6 months	Water management section

during the follow-up period till March 2010.

Step 4: Holding the gains. A surveillance checklist was incorporated to ensure cleaning of the OT premises, fortnightly microbiology test, 3-monthly cleaning of the water tank, and filters of the air-handling unit (Table 3). A laboratory protocol was made to subject all specimens of pus/discharge from SSI to Gram stain, Ziehl-Neilson stain, and routine culture initially. If the tests are negative or if acid fast bacilli are detected, culture in Lowenstein-Jensen medium is to be carried out and antibiogram tested for the mycobacteria grown. After the QIP over the next 5 years (from August 2009 to March 2014), 628 pacemaker implantation procedures were carried out. There were two isolated cases of superficial SSI in the year 2012 and 2014 caused by *S. epidermidis*, but EMB infection did not recur. Our experience was shared with another hospital in an outlocation that experienced similar type of SSI in an OT. The QIP methodology was implemented with an equally successful result.

4. Discussion

Infection after a clean elective surgical procedure like permanent pacemaker implantation is expected to be low; and SSI after the implantation of an expensive cardiac device causes much anguish to the patient and the implanting physician. Superficial SSI due to common skin organisms is often easy to treat and prevent by reinforcing aseptic surgical norms. This series of four patients with SSI due to an uncommon organism such as EMB posed a great challenge to treat the individual cases and trace the organism to its source. Even after getting the report of AMB, we did not have an immediate clear solution to the problem. Therefore, we applied the step-by-step approach of a QIP. Our cross-functional team comprised of clinicians, nurses, technicians, microbiologist, water management staff, air conditioning staff, and administrators who analyzed and interacted.

Pacemaker pocket infection due to EMB is very rare.[11,12] Nosocomial SSI caused by EMB has been reported in cardiothoracic, laparoscopic, plastic surgery, and joint replacement units.[13–16] There was considerable delay in attributing the infection to EMB in our series as well as in other reports due to its rarity, low index of clinical suspicion, and varied time to manifest that ranged from immediately after surgery to as long as 2 years. Systemic features like fever are known to be remarkably absent. The first clue for SSI caused by the unusual pathogen was frank purulent discharge from which no bacteria could be isolated from routine tests and the lack of response to anti-Staphylococcal antibiotics. It should prompt Ziehl-Nielson staining of pus to identify mycobacteria as rods. *Mycobacterium tuberculosis* and *Mycobacterium leprae* are well known to cause human infection. The rest more than 50 species of mycobacteria are collectively known by various names – AMB/non-tuberculous mycobacteria/mycobacteria other than tuberculosis.[5] The broad term AMB includes species with four types of infective potential: pathogenic to animals, opportunistic infections in humans, non-infective saprophytes, and saprophytes with pathogenic potential. The saprophytes with pathogenic potential grow in water and dust and cause SSI due to contamination. Outbreaks of SSI due to contamination of endoscopes, cardioplegia solution, and methylene blue have been reported.[13–16] Person to person transmission of EMB infection does not occur. Based on the rate of growth in culture medium and pigmentation, Runyun classified AMB into four groups.[17] Groups 1, 11, and 111 are slow-growing bacteria that take more than 2 weeks to grow in culture medium.

I. Photochromogens – produce pigment when exposed to light, e.g. *Mycobacterium kansasii*, *Mycobacterium marinum*, and *Mycobacterium simiae*
II. Scotochromogens – get pigmented in darkness, e.g. *Mycobacterium scrofulaceum*, and *Mycobacterium szulgai*
III. Nonchromogens – do not produce pigment, e.g. opportunistic pathogens including *Mycobacterium avium* complex, *Mycobacterium ulcerans*, *Mycobacterium xenopi*, etc.
IV. Rapid growing mycobacteria (RGM) – grow within 3–5 days, e.g. *M. fortuitum* and *M. chelonae/abscessus*.

Several species of EMB that are ubiquitous in nature belong to the group of RGM. The colonies of non-infective saprophytes are pigmented and the colonies of potentially pathogenic species like *M. fortuitum* and *M. chelonae/abscessus* lack pigment. Identification of the type of mycobacteria by the above-mentioned broad guidelines should be possible in any health care service with basic laboratory facilities. Accurate species differentiation would require polymerase chain reaction-restriction enzyme analysis (PCR-REA).

The EMB are resistant to the usual anti-tuberculous drugs; therefore species differentiation and antibiotic sensitivity are essential for treatment.[5,18] There are reports for successful treatment with ofloxacin and various combinations of clarithromycin, amikacin, sulfonamides, ciprofloxacin, doxycycline, linezolid, etc. for prolonged periods ranging from 3 weeks to 3 months or even longer.[5,6,18,19] The third patient in our series responded to frequent wound dressing and empiric treatment with linezolid and ciprofloxacin for 6 weeks. Deep SSI would require an aggressive surgical approach by wide excision, debridement, and removal of the implant.[11,12,19] In the first and fourth patients, the infected pacemakers were removed and new pacemakers were implanted on the contralateral side with good outcome. However, in the second patient, due to financial constraints, we resorted to reimplantation of the same pacemaker in the contralateral side after ETO sterilization. The infection recurred on the contralateral side also and the infection subsided only after removal of the pacemaker and debridement. By then, the first side had healed and a new pacemaker was implanted there. There are several reports of reusing pacemakers explanted after death with satisfactory results. Reuse of pacemaker/device removed due to infection is not to be practiced since it carries a high risk of harboring deep SSI in the pectoral muscle bed and loss of site for implantation. In our patient, we could use the original side, but we do not recommend reuse of pacemakers explanted due to infection. The usual methods of OT sterilization and the amount of chlorine in municipal water supply are not sufficient to eradicate mycobacteria.[4,5] We could eliminate the mycobacteria by cleaning the tank and chlorine enrichment

for a short period. However, for regular preventive maintenance, superchlorination once in 6 months is recommended.[20] It involves enriching the chlorine content in water tanks to 10 ppm and allowing the water to run through the pipelines for about 5–6 h so that biofilm that tends to form in the interphase between water and solid surfaces can be eliminated/prevented. Biofilm is a potential site for harboring organisms that can cause nosocomial infection. Superchlorination should be conducted at a time when water consumption is the least; Sundays from 2.00 PM to 7.00 PM. Care should be taken to avoid pipelines for hemodialysis units and to provide alternate source of drinking water during the 6 h.

Through this QIP, we could trace the outbreak to contamination of the OT with rapid growing non-pigmented EMB from the water tank. We speculate that persistent mycobacteria in the water source and an increase in the bacterial load in a short period led to the outbreak in patients who underwent consecutive pacemaker implantation during that time. Literature search on the subject gave us a direction to curtail the outbreak through structured protocol and surveillance.

5. Conclusion

Water-borne nosocomial infection is an emerging global problem that needs to be recognized and addressed at local level.[6] Microbiology report using the nomenclature of EMB, rather than AMB, will generate awareness to suspect the infection as a consequence of contamination. Infection with EMB does not respond to the usual anti-tuberculous drugs and antibiotic use must be guided by antibiogram. Prolonged course of treatment and even wound debridement may be required to eliminate the infection. As a preventive measure, we recommend 3-monthly cleaning of water tanks connected to operation theaters and 6-monthly superchlorination of water tanks and pipelines.

6. Limitation

Due to lack of facility for RT-PCR (real time PCR for the detection of mRNA), we could not identify the specific type of EMB.

Conflicts of interest

The authors have none to declare.

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