

December 15, 2008

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Ms. Jackson;

Pacemaker Club is an online community of pacemaker and implantable cardioverter defibrillator recipients. The Club was founded in 2000. Our purpose is to help cardiac device recipients meet, share information and support each other. Our membership includes over 8,700 people who are mainly patients and loved-ones of recipients. The majority of our members reside in the United States.

Our members, more than anyone, understand the importance of the surgical care associated with implanting cardiac devices - including the infection control measures that should be followed during a procedure.

I understand that Medicare is considering implementation of a non-payment policy to providers for pacemaker and cardioverter defibrillator implant related infections. As a recipient and Founder of Pacemaker Club, I applaud this initiative as it should motivate providers to seriously measure infection rates and research the causes of infection, as well as lead to better medical guidelines designed to prevent infections.

Recipients are the ones that bear the trauma, heartache, and long term care associated with having to remove and treat a pacemaker and cardioverter defibrillator implant that has become infected. By following appropriate infection control guidelines, many of the preventable infections can be minimized or even eliminated.

Infection is one of the most common complications that is discussed by our members in our online forums. As a recipient, it is alarming to read articles that show the rate of infection increasing much faster in recent years than the rate of implantations. I have enclosed stories from a few of our members who have experienced infections. Their personal experiences clearly show the pain and suffering that infection can cause patients and their loved-ones. I ask that you seriously consider the well-being of Pacemaker Club's current and future members, as well as all recipients, when reviewing infection related policies.

Sincerely,



Blake Hunter

Founder, Pacemaker Club

Attachments

Elaine's Story

Thousand Oaks, CA

I joined Pacemaker Club a few years ago; because of my frustration with the care my dad was receiving earlier this year.

My dad developed an infection which was dismissed by his cardiologist as a "skin infection". He was otherwise active and healthy, albeit elderly. His cardiologist sent him to a dermatologist for treatment. The dermatologist tried to maintain his composure as he told my parents to run, not walk, to a different cardiologist, to treat the pacemaker infection. After having had an infection for a week, finally somebody had enough sense to put him on IV antibiotics for a few days.

The Wednesday after they got the infection under control, he went in to have the pacemaker replaced. During the procedure, the surgeon could not remove one of the leads. He used a laser to free the lead but that caused massive bleeding. They opened-up his chest to harvest a piece of his pericardium to patch the hole in his vena cava, left by the lead. What was supposed to be no more than a two-hour operation, lasted into Thursday morning. Finally, after 14 units of blood, he was out of surgery and into intensive care.

My sister-in-law called to tell me that she didn't have a good feeling, and said she really thought that my sister and I should "get down there". Luckily I am a pilot, so I flew my sister and myself to Temecula in under an hour, atop Los Angeles rush-hour traffic. We got there in time to see my dad, alive, on Thursday night, but he died Friday morning.

I'm not sure if he was ever told what happened to him... why he went in relatively healthy and came out with a zipper on his chest, only to meet his maker several hours later.

Sandy's Story Greeley, CO

I first received a pacemaker in October of 1997. I had been having fainting spells and was diagnosed with complete heart block. I believe the damage to my heart was caused from my having Lupus. I am currently 47 years old.

My pacer was pretty much trouble free until the Spring of 2006. At that time one of the leads was found to be broken and the battery had been drained by it. Rather than just put in a new lead and battery they opted for a completely new pacer and lead. They left the old, broken lead in the artery, just hanging out, and continued to use the other line that was working fine.

In September of 2007, I started experiencing a great deal of pain in my back. I went to my primary care giver who sent me to the hospital with a possible blood clot. What they found was my pacemaker and all three leads covered with a MRSA infection, as well as vegetation on my heart. The blood clot was part of the infection that broke off and went to my lung. I was one very sick patient.

From the time I started hurting I was absolutely miserable. I became so weak, so fast, that I couldn't even make it to the bathroom. All I could do was sit bundled up in a chair as it was more comfortable than lying down, and try to conserve energy. I looked like death, and sounded like it too, as I hardly had the strength to speak.

The cardiologists did some more scans and determined that all parts of the pacer needed to be removed. They sent me to a specialist in Denver who uses a laser to kill the MRSA and disconnect the wires from inside the arteries. The other option was to have my chest opened and work on the problems through that way. The laser procedure went well until the final line was being taken out. The doctor was at the point that he was having the other surgeon scrub in for the open-chest procedure, when fortunately he tried one last maneuver and it worked. I am very grateful for this, as I was so weak that I probably would not have survived the open-chest procedure. The next thing I knew I was in the ICU having my chest tube removed. I stayed at the hospital about 5 more days, and then was transferred back to my hospital in Greeley.

I stayed in the hospital for about two more weeks. I received Vancomycin IV at first, but developed an allergy to it, so was switched to Daptomycin. I developed a blood clot in my arm, near where the pacer had been, and while we waited for that to reconcile itself I tried to get some of my strength back. Eventually I was stable enough to go home, with the caveat that I was not to be left alone, and that I couldn't drive. I was scheduled to have a new pacemaker implanted once I had been on the antibiotics for a month and there was no sign of MRSA. I had the new pacer and leads implanted on October 31, 2007 and I was not put on any antibiotics at that time. The pacer was put on my right side, away from the spot on the left side where the old one had been.

Nine days later a metal pin in my foot became inflamed. The surgeon, knowing about the recent MRSA in my pacer, opted to remove the pin the next day. It also had the MRSA infection on it and in the tissue around it. I was put back on Daptomycin IV and sent home,

Two weeks later I began experiencing incredible pain in my back again. Thinking that the pacer might be infected they immediately did scans to see what was up. The new pacer was fine, but my T7 and T8 vertebrae were nearly eaten away along with quite a bit of other damage done once again by MRSA. From that point on, it has been a long haul. I had two surgeries and was in the ICU sedated for a month. I had a month of inpatient rehab, went home in a wheelchair, but have slowly progressed to using a can and braces on my legs.

My gut feeling is that even though they test for the presence of infections like MRSA, and they don't show up, they are still in the body somewhere until something sets them off. It would seem to me that testing for bugs before implants/surgery, should become more of a protocol in the prevention of pacemaker infections.

Valerie's Story Anaheim, CA

My 2006 Christmas has to be the most memorable one yet. I had my pacemaker removed because it was infected.

My doctor called me on December 19th and said to go to the Emergency Room (ER) in Cedars-Sinai. That way, I could be admitted and he could run some tests and I could be seen by an infectious disease doctor. Little did we know that we would be spending Christmas in the hospital ICU.

At the ER, they called the infectious disease doctor. He took one look and said, "Well, I think you are going to have to stay with us for awhile, because this looks like it is not going to get better". That was very shocking news. So, that night, I was admitted to the normal hospital ward, and was scheduled for my pacemaker removal the following morning, December 20. From that point, things got worse.

The plan was to remove everything from my muscle and send me home the next day with my PICC line still in to continue the appropriate antibiotics. Then, after about 6 weeks, they would implant another dual pacer on my right side. However, things didn't go according to plan.

The doctors went to take out my pacemaker during surgery, and right when they disconnected the leads, my heart stopped beating completely. This was not supposed to happen since I still had some electrical activity before the implant. So they were shocked. They quickly had to start pacing my heart until I was stable.

Then, they had to place the pacemaker outside and the wires coming down from my vein in my neck. I also lost a lot of blood during the procedure, but the worst part was I remember coming out of sedation during the procedure.

I was transferred to the CICU where I spent 4 days completely paced, and on Christmas Eve and Christmas day, my heart started beating on its own again, but it still was a weird rhythm. My doctors were happy about that because at least they knew that my heart was getting stronger. BUT THEN, my heart all of a sudden stopped beating again and thankfully they placed that temporary pacemaker on my neck because from then on, I was completely paced again! The doctors have no explanation for this; they were stumped. On December 26, I went in for my implantation on my right side. This time they were prepared in case my heart stopped.

They left the temporary device on my neck until they got a good attachment from the pacemaker in my shoulder. Once they got that, they were able to remove the temporary pacemaker from my neck. When I woke up, I was so confused as to why I had horrific pain in my right eye! I had to think back "was I here for eye surgery? It turned out that the anesthesiologist had placed an oxygen mask on me that was way too large. The mask

had scraped the cornea while I was sedated. I didn't know what hurt worse, the incision or my eye!

The good news is that my infection eventually cleared up and that I survived. My family had our own Christmas day when I got better and even opened up presents. I thank God I am here today and I am so blessed to have a wonderful family.

PK's Story California

I was born with a congenital bicuspid aortic valve. I opted to have valve replacement surgery because I was very symptomatic of stenosis, even though measurements on the valve were not in the severe range. I had gotten to the point that I was having chest pain with little exertion - which didn't match the degree of damage to the valve, so it was suspected that something else was going on as well.

I had the valve replacement surgery in June 2008. I woke up from surgery with an external pacemaker, and was told that I had to have part of my aortic branch replaced and also a septal myomectomy for a condition called SAM. I was told this interrupted the conductivity of my heart, and that we'd wait a few days to see if it would heal itself. It did not.

I was in ICU for 1 week, and had the external pacemaker for about 11 days. I still had total "heart block". I had a permanent pacemaker implanted on my left side on day 11. By day 13, I noticed splinter hemorrhages in fingernails, and feeling flush. I was released from the hospital on July 13th. By the 14th, I was feeling very flush (aching body, nausea, irritable) and my temperature was up to 101.6, so went to Emergency Room (ER). They took blood cultures, gave pain meds, and antibiotics for a suspected urinary tract infection. The morning of the 16th I was called and told to immediately return to the ER due to positive blood cultures.

I was in the hospital a few more days while culture grew out. It was Staph Epidermis. Endocarditis was also suspected, so I had a TEE, which revealed vegetations on the leads of the pacemaker. I had to wait a week for a doctor who was qualified to remove pacemakers was available, and I was transferred to a different hospital.

While in the hospital, my treatment included Rifampin, Vancomycin, Heparin and one other IV antibiotic. The infection caused extreme pain throughout my body accompanied by irritability and psychosis which could not be controlled with IV diladid and fentonil. I was also put on anti-anxiety meds which caused nausea, and then put on anti-nausea meds, too.

When the pacemaker was removed, no cultures grew from the leads. I had a replacement device implanted one week later. My recovery has been terrible. My husband had to take time off of work - the entire month of August - to care for me. I grew very weak and couldn't walk. I'd become very anemic from all the drugs and had to have blood transfusions, as well as weekly trips to the infusion clinic for Pic Line dressing changes. I was seen at home almost every day by a nurse for blood draws.

I'm not yet back to work and will be indefinitely under an Infectious Disease Doctor's care. Also, for some reason, this pacemaker and leads seem to be irritating my heart, so I was put on the maximum dose of Lopressor to help control PVCs and rapid heartbeat. I was told that this could happen with a right-side implant. It is very uncomfortable, but I

am getting used to it. More than anything, the barrage of drugs I was given to treat the infection has done the most damage - hair loss, light sensitivity, skin discoloration, anemia, high liver counts, and facial neuralgia.