TRANSCRIPTION

cpsi Canadian Patient Safety Institute iscp Institut canadien pour la sécurité des patients Carola Bravi Patients for Patient Safety Canada

[0:00:09] My son was born in 1994 and he had a heart murmur, which never caused him any problems. Nicholas had a condition called Wolf Parkinson White Syndrome. And essentially what that is, is an extra electrical pathway in his heart. So when his heart rate would get caught up in that, it would go 180 to 240 beats a minute.

[0:00:35] April 1st, 2010, he called me from school and said, "Mom, I don't feel very good. My heart feels funny and my chest feels funny." So I picked him up at school and checked his heart rate and I could feel it, but it felt a little erratic. Took him to emerge, and as soon as she hooked him up to the equipment, they saw that his heart rate was at 180. And so they immediately swarmed around him, got him all hooked up, and he was able to stabilize under medication. And then his procedure was scheduled at Children's for April 28th. And what he was scheduled for was a cardiac ablation, which means they insert catheters through the femoral artery in the leg and they feed them up through a sheath. And there's about four catheters, takes about four to five hours, and they map out the electrical systems of the heart, the pathways.

[0:01:28] I felt pretty good about the procedure because I've worked in health care for 27 years and my last four years in health care have been in the O.R. And I've seen situations where, you know, things have gotten a little critical, but the staff are great, and I'm very comfortable around health care facilities. And actually, so was Nicholas.

[0:01:53] When we brought him into the room, it was in the cardiac cath lab, which is not an O.R. theatre. They said, "Oh, don't worry, it'll be a few hours and he's in good hands. He'll be okay." And I trusted that he would be okay. But then I went, "Oh, don't rush, you know, don't rush." And out I went.

[0:02:11] So about three and a half hours later, I came back to the hospital. I went out for a bit and came back and asked the nurse if she could check to see how Nick was doing. And she went and checked and she said, "Oh, the ablation has just been done so it won't be long now. He'll be out soon." And I was like, "Perfect. So about 20 minutes." So I ran out to my car to grab my book and came back in and there was a lady waiting for me and she said, "Are you Mrs. Bravi?" And I said, "Yes." She said, "Oh, something's happened." And I just said, "Oh my God, is he alive?" And they said, "Well, they're working on him." I just said, "Well, get back in there. I want to know what's going on. You go tell me." I wanted her to update me.

[0:02:58] So she went back out, came back in and said, "They've taken him to the operating room." And so then I knew that it must have been real serious. During the procedure, from my understanding how Dr. Santini explained it is once he had all the catheters in place and they mapped out the pathways, they have to trigger the extra pathway. When they triggered it, his heart raced, which is standard and normal procedure. They had to shock him to get him back down to normal rhythm in order to burn that extra pathway. When he burned the extra pathway, unbeknownst to him, an arcing occurred to the opposite side of his heart from where the burn occurred. So instead of having one burn where the ablation, he now has four. He has one burn where the ablation occurred, and he has three other ones at the top of his atrium. One burned right through and that was the critical burn.

[0:04:00] So now he has this hole in his heart and your heart continues to beat and the blood fills the heart sac and it gets to a point where it compresses the heart that it cannot beat. They pick this up by ultrasound. They did an emergency ultrasound which showed that there was all this fluid around his heart. So one of the ways to relieve the pressure from the heart is to stick a needle through the chest wall and try to drain it. They tried that. It was unsuccessful.

[0:04:31] So they actually cut a little window. It's called a pericardial window. They make a little hole in the sac wall, which relieved the blood pressure. And now his heart could beat. One of the things that can happen is you could perforate or put a hole while you're putting the catheters in. That's the first thing that Dr. Santini thought may have happened. So when they did the pericardial window, they put the scope in and there was no bleeding from the bottom ventricles of the heart. So then they had to do an emergency strenotomy [ph].

[0:04:55] It took about an hour and a half for Nicholas to come out of the O.R. and be stabilized enough for us to see him. He was admitted to the ICU unit. He was put on a ventilator and kept hypothermic. Because of the issue with the lack of blood flow through the body, there was a concern that he could possibly have brain damage.

[0:05:19] The anesthetist came by the next day and told me that he wanted to check out Nicholas' neurological status. So when the anesthetist came in and said, "You know, Mrs. Bravi, I'd like to check your son's neurological status because he suffered quite the assault yesterday," and those were his words, and I remember thinking, "Wow."

[0:05:38] When Nicholas was home, he had a Stery strip down the front of his chest covering the incision site. And one day – I think it was two weeks later or a week later – he was in the shower and he took the Stery strip off and he came walking out of the shower and he had this scar and it was really red and it was so shocking. I hadn't seen it. And the thing that really stood out for me was that his car was crooked. It was crooked. And so I knew that they were in a hurry. And you know, it just kind of really hit me hard that this was a life-threatening, critical event that affected the staff just as much as it probably

affected me. I knew it deep in my heart that he was going to be okay. But now my whole thought process was, "What the heck happened?"

[0:06:44] I started asking questions of the surgeon the next day. And he'd already gone online and researched, apparently, from what he told me. And there was no other report of this ever happening. In fact, even the manufacturer, the original manufacturer of the device, had never heard of anything like that happening. And so Nick was the one. It's not even one in a million. He was the one. And I just found that hard to believe.

[0:07:08] Dr. Sanatani went and checked, and he did confirm that the the device in Nick's atrium was, in fact, a sent product, a reprocessed medical device, a reprocessed, single-use device. My understanding is that a single-use should only be used for single-use only and then disposed of. Reprocessed device means it's been reprocessed either within Canada in-house, but then they also have third-party reprocessing, which is actually single-use devices that get shipped to the States and get reprocessed there and then sold back as a service, not as a device manufacturer.

[0:07:54] I came to the conclusion that it might be the device by the fact that it was in situ in his right atrium where the burns occurred. And I know from working in the O.R. that reprocessing is an accepted form of practice in British Columbia. And I kind of fixated on that. I thought, "I really hope that my son's device was safe if it had been used before." I found out after the fact, actually, months later, that my son's device had been used four times previously. Upon my researching these single-use devices that are reprocessed, there were a lot of concerning gaps and tracking details which nobody could tell me about. I could not find a single report on the Medwatch system about a reprocessed medical device. That started me thinking that, "Why hasn't this been reported?" And so I report it.

[0:08:55] And my thought process was, Well, if nobody knows about it, nobody's reporting it because nothing is mandatory. And that's a clear gap. I trust our health care system in the sense that I will get good care when I'm in the hospital. But as a patient and as family members, you have to be your own advocate. You really do. Just keep your eyes open and your ears open. And if something doesn't feel right, then you have to ask the guestion.

[0:09:27] And I think the culture in health care has been, you don't ask. You're just thankful that your child is alive. And it's rude to ask and to push as though something went wrong. Well, something did go wrong.

[0:09:40] Because of the knowledge that I was gaining from my investigation, there was some good that did come out of this. And Dr. Sanatani now pulls the catheters down before he shocks a patient. He no longer uses reprocessed catheters. *He* doesn't. And that's great.

[0:10:03] Nicholas is now a robust 19-year-old living his life up in Kamloops with his girlfriend and having to pay the bills. I'm thankful that he's having to struggle paying his bills because it means that we still have him with us.

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