



Case Report

Routine replacement of a vagal nerve stimulator generator leading to asystole

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ABSTRACT

A 52-year-old female with a longstanding history of drug-resistant epilepsy that included focal impaired awareness seizure presented at end of service of her vagus nerve stimulator (VNS) generator. She had undergone a generator replacement in 2010 without complication. However, her latest replacement was accompanied by multiple bouts of asystole. We discuss the case, possible causes of the asystole, and its relevance to the future of VNS generator replacement and epilepsy treatment.

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1. Introduction

Drug-resistant epilepsy remains one of the most common neurological conditions, as well as one of the most challenging. Even as understanding of the etiology improves, epilepsy remains troublesome for both the patient and physician to treat. An estimated 1% of the population suffers from epilepsy, with one-third left uncontrolled by two or more anti-seizure medications or other possible therapies [1]. In this drug-resistant population, in which seizure freedom is unlikely, vagus nerve stimulation (VNS) remains an effective adjunct therapy. Multiple studies have demonstrated its effectiveness including Révész et al. who investigated the effects of 130 patients implanted with a VNS between 2000 and 2013 and showed an increased response rate from 22.1 to 43.8% from the first and fifth year of implantation regardless of pharmacological anti-seizure drug (ASD) treatment changes [2].

Generator replacements continue to increase given the use of the device since its FDA approval in 1997. Generator replacements are expected to be straightforward in the population obtaining efficacy and wishing to maintain longevity of their therapy. This case report will describe a typical replacement for end of service that led to asystole in the patient from VNS therapy with an upgraded model.

2. Case presentation

A 52-year-old female with a longstanding history of drug-resistant epilepsy that included focal impaired awareness seizures presented at the end of service of her VNS generator. She received her first VNS in 2006 and subsequently underwent a routine generator replacement in 2010 without complication. The patient had achieved significant seizure reduction and was adjusted to one anti-seizure medication since the implantation of the device. Given this, she was scheduled to have her Model 103 generator replaced with the newest model, Sentiva (Cyberonics Model 1000).

The procedure for replacement was performed under light sedation and local anesthesia. There were no visible abnormalities observed in the lead, old generator, or new generator during the replacement. The impedance and system check returned within normal limits (1741 Ohms) following connection to the new device. Intraoperative programming, as seen in Table 1, was duplicated from settings on the old device.

Upon turning on the new generator intraoperatively, the patient sustained an asystolic event that lasted approximately 2–3 s before returning to normal sinus rhythm. Normal sinus rhythm was maintained for the remainder of the procedure following this single event. Secondary to this, the case was continued to closure and the patient was brought in stable condition to the recovery room. During the 30 min recovery period, the patient sustained two similar episodes of asystole lasting several seconds, but remained stable. The patient remained conscious and unaware during both events. At this point a discussion with cardiology deemed the patient stable for discharge with appropriate follow-up. Subsequently, the patient experienced a syncopal episode several times at home over the next 36 h and then returned to the emergency room. After admission, it

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Table 1

Post-operative programming for sentiva model 1000SN 11,957.

Generator output:	
Current (mA)	1.75
Frequency (Hz)	25
Pulse width (μs)	250
On time (s)	30
Off time (min)	5
Magnet Output:	
Current (mA)	2
Pulse width (μs)	250
On time (s)	60

was determined that the episodes correlated with the onset of stimulation from the new generator. Therefore, the generator was turned off and symptoms completely resolved for several days on telemetry.

The decision was made to replace the newer Sentiva model, with her previous technology, VNS Model 103. She underwent routine replacement with the device left off during the procedure. With the patient monitored by telemetry in the post-operative period, the settings of the VNS Model 103 were slowly increased over two days to her previous settings as shown in Table 1. During this process, the patient did not experience any episodes of asystole, or abnormal rhythms and was discharged with no further sequelae. The generator, Model 1000SN 11957, was sent back to the manufacturer for evaluation. The returned full report found no issues or abnormalities with the generator.

3. Discussion

Typical surgical complications of VNS implantation include infection, vocal cord palsy, and postoperative hematoma, as well as pain and sensory-related complications as demonstrated by Révész et al. [3]. The largest complication from surgery was shown to be due to hardware complications (3.7%). Asystole has not been found to be related to hardware malfunctioning, and it is not typically a surgical complication of VNS for either initial implant or replacement. Understanding the complications and nuances of VNS generator replacements is of importance to the physician given the increased time these devices are implanted and administering efficacy.

VNS is not expected to lead to cardiac events as there should not be efferent stimulation of the vagus nerve cardiac fibers. Cardiac events, specifically in this patient population, may be secondary to addition or change in medications, or change in seizure patterns. In our case, the programming parameters had remained constant, the patient was conscious during many of her episodes of asystole, had no documented seizures, and her AED regimen was unchanged prior and after the procedure for an extended time period.

Review of the literature demonstrates the rare incidence of bradycardia or asystole during initial implantation which can be referenced as 0.1% [4]. This occurs during intraoperative lead tests and has led to

aborting the implant. There is also a case report of similar events occurring in a delayed fashion 9 years after initial implant without change in therapy or device [5]. It could be theorized that these described cases are secondary to patient anatomic variation and response to the therapy. To our knowledge, this is the first report of episodes of cardiac arrhythmia or asystole occurring secondary to replacement of the generator and subsequently being device related since it resolved with replacement back to an older technology.

4. Conclusion

Through an unclear mechanism, this case illustrates the possible concern for a cardiac arrhythmia or asystole that can occur surrounding VNS devices. Although similar episodes rarely occurred in the literature, it was previously thought to be anatomic variation in patients during an initial implant. This case report demonstrates a possible device-related effect in newer technology in a patient already established with VNS therapy. With an expected increase in replacement population for the future given the longevity and efficacy of these devices, the ability of the physician to understand and have a plan in place for suspected complications is imperative to maintain sustainable appropriate patient outcomes.

Declarations of interest

Dr. Falowski serves as a consultant for Abbott, Vertiflex, Medtronic, and Nevro and conducts research for Abbott, Medtronic, Saluda, and Nuvectra. The remaining authors have no conflict of interests.

Ethical statement

Vagal nerve stimulator generator replacement is routinely performed in clinical practice. The patient was informed about the procedure. Written and verbal consent obtained before performing the replacement with the privacy right of the subject is observed.

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