

# Anesthetic Management for Implantation of a Treatment Device: The Rheos Baroreflex Hypertensive Therapy System

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Resistant hypertension is a prevalent dilemma. Despite all available antihypertensive medications and multiple strategies such as healthier diets and exercise programs, many patients are still unable to maintain or reach a therapeutic goal for systolic blood pressure. Because of this major health concern, CVRx, Inc has developed a treatment involving baroreflex activation therapy (Rheos Baroreflex Hypertension Therapy System) to treat patients with uncontrolled high blood pressure. The surgical implantation of this system is similar to a carotid endarterectomy procedure; however, the anesthetic management for this procedure is unique and challenging.

This case report describes a 45-year-old African American woman with a history of hypertension who was receiving multiple antihypertensive medications

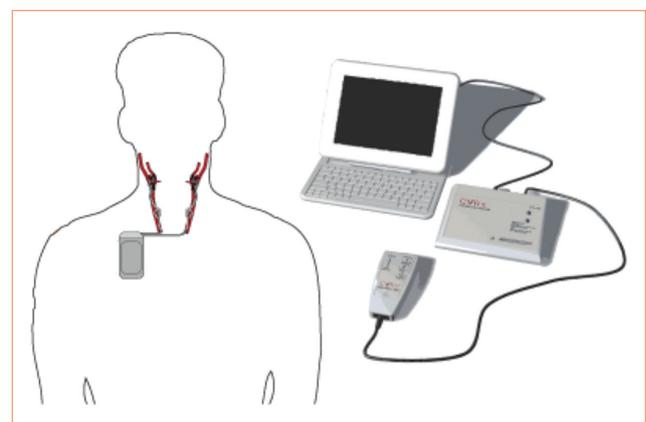
and, thus, was a qualified candidate for implantation of this device. The goal of anesthetic management during implantation of this hypertension therapy system is to preserve the carotid sinus baroreceptor sensitivity by avoiding administering anesthetic agents that inhibit the baroreceptor reflex during electrode placement and the testing period. Because of the restriction of some of the anesthetic agents that an anesthesia provider can use, this procedure poses major challenges to the anesthesia provider in planning for anesthesia care and managing risks to the patient.

**Keywords:** Baroreflex, hypertensive therapy, resistant hypertension, Rheos Baroreflex Hypertensive Therapy System.

Resistant hypertension, described as a systolic blood pressure above 160 mm Hg and a diastolic blood pressure above 100 mm Hg, is a prevalent dilemma in today's medical world.<sup>1-3</sup> High blood pressure can cause small blood vessels to become damaged and less effective in supplying the body's vital organs with oxygen and nutrients.<sup>2,3</sup> Each increase of 20 mm Hg in systolic blood pressure or 10 mm Hg in diastolic blood pressure above the normal level (120/80 mm Hg) puts individuals at risk of stroke, ischemic heart disease, kidney disease, vascular diseases, and death.<sup>2,3</sup> Resistant hypertension is known to be highly associated with morbidity and mortality.<sup>1</sup> Despite all available antihypertensive medications and multiple strategies, such as healthier diets and exercise programs, many patients are still unable to maintain or reach a therapeutic goal for systolic blood pressure.<sup>1</sup> Because of this major health concern, CVRx, Inc (Minneapolis, Minnesota) has developed a novel treatment involving baroreflex activation therapy (Rheos Baroreflex Hypertension Therapy System) to treat patients with uncontrolled high blood pressure.

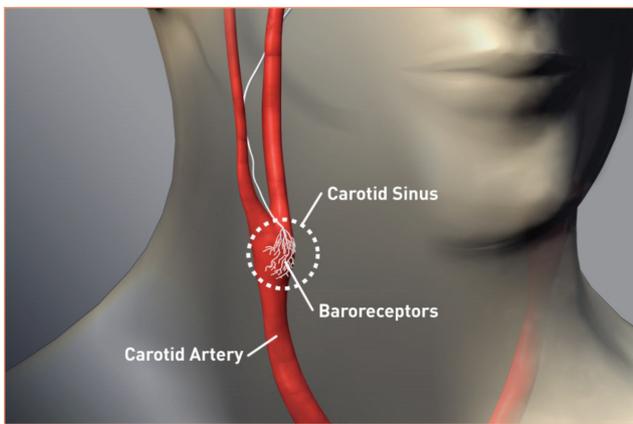
The Rheos Baroreflex Hypertension Therapy System (Figures 1 and 2) is an implantable device that consists of 3 components: an implantable pulse generator (IPG), carotid sinus leads, and the programmer system.<sup>2-4</sup> The

function of the IPG is to control and deliver the activation energy to the patient's carotid sinuses via the carotid sinus leads.<sup>2-4</sup> The programmer system is then used to communicate noninvasively to the IPG.<sup>2,4</sup> The objective of this technology is to take advantage of the body's own natural blood pressure regulation system to maintain homeostasis.<sup>2,4</sup> Figures 3 and 4 show how the Rheos Hypertension Therapy System mimics the body's blood

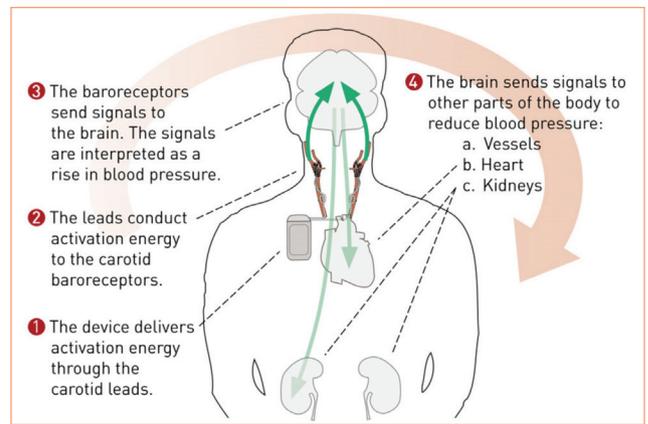


**Figure 1.** Rheos Implantable Pulse Generator With Rheos Carotid Sinus Leads (left) and Rheos Programmer System (right)

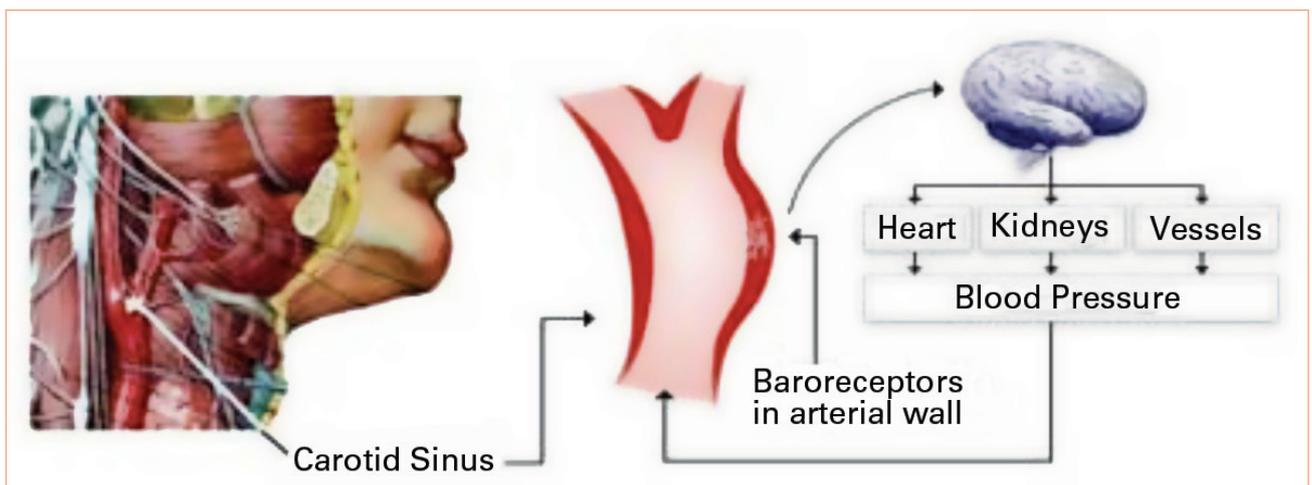
(Reprinted with permission from CVRx, Inc.<sup>6</sup>)



**Figure 2. Anatomy of Baroreceptors**  
(Reprinted with permission from CVRx, Inc.<sup>6</sup>)



**Figure 3. How the Rhoes System Works**  
(Reprinted with permission from CVRx, Inc.<sup>6</sup>)



**Figure 4. Physiology of Blood Pressure Regulation**  
Baroreceptors provide feedback control of blood pressure and nervous system activity.  
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pressure regulator by electrically activating the baroreceptors that sense an aberrant increase in the blood pressure level.<sup>2,4</sup> When the baroreceptors are triggered, signals are sent to the central nervous system and interpreted as a rise in blood pressure.<sup>2,4</sup> The brain, in its natural way, directs the body's own control mechanisms to counteract this perceived rise in blood pressure by sending signals to other organs such as the heart, kidneys, and blood vessels to reduce the blood pressure.<sup>2,4</sup> The result is a reduction in blood pressure that could prevent stroke, heart attack, heart and kidney failure, other related diseases, and death.<sup>4</sup> Whereas sympathetic hyperactivity is often the trigger for hypertension, the carotid baroreflex counterbalances the sympathetic tone and helps maintain cardiovascular stability.<sup>1-7</sup> The Rhoes treatment option is still under clinical investigation to determine its safety and efficacy in lowering blood pressure.<sup>2,4</sup>

The surgical insertion of the Rhoes system poses many challenges for anesthesia providers. One of the challenges is choosing the appropriate anesthetic agents. The

employ of anesthetic agents is extremely selective to preserve the carotid sinus baroreceptor sensitivity during the electrode placement and testing.<sup>4-6</sup> The following case study presents some difficulties an anesthesia provider might encounter while providing anesthesia to patients who undergo this procedure.

### Case Summary

A 45-year-old African American woman, weighing 116 kg and measuring 178 cm tall, presented at a Trauma 1 level facility with a history of severe hypertension, and she was placed on multiple antihypertensive medication regimens. The patient was a qualified candidate for implantation of the Rhoes system because of uncontrolled hypertension despite receiving metoprolol, hydralazine, clonidine, furosemide, lisinopril, and hydrochlorothiazide. In addition to these antihypertensive medications, the patient was also receiving metformin, insulin glargine (Lantus), insulin lispro (Humalog), simvastatin, tramadol, alprazolam, esomeprazole (Nexium), a multivitamin

with iron, and black cohosh for other systemic diseases. Comorbidities included a high body mass index, anxiety, diabetes, and a heart murmur that required antibiotic treatment. As consequences of hypertension, obesity, and diabetes, the patient experienced shortness of breath, hyperlipidemia, peripheral vascular disease, hiatal hernia, and gastroesophageal reflux disease. According to the cardiovascular surgeon's instructions, the patient stated that she had not taken any of her antihypertensive medications the morning of her surgery. The preoperative blood pressure read 186/105 mm Hg, and the heart rate was 66/min. Other pertinent laboratory results and studies (electrocardiogram, ultrasound/Doppler, chest xray) were unremarkable. According to the patient's review of systems along with her past medical and surgical history, an ASA physical status of III was assigned.

The patient appeared calm and pleasant. She expressed dissatisfaction with taking multiple antihypertensive medications daily and was eager to be a subject for this clinical trial. She demonstrated a thorough understanding of the device, the procedure to implant the device, and the anesthesia care plan. Knowing that this was a clinical trial, anesthesia providers for this case sought out the Rheos implantation protocol. According to the Rheos implantation protocol, healthcare and anesthesia providers were not to alter the blood pressure or heart rate by administering any medications.

En route to the operating room, the patient was premedicated with 2 mg of midazolam intravenously (IV). Immediately on arrival to the operating room, the patient was transferred to the operating bed in supine position. All standard monitors, including pulse oximetry, noninvasive blood pressure monitors, and electrocardiography, were applied. The initial vital signs were obtained, with a systolic blood pressure above 200 mm Hg and a diastolic blood pressure in the low 100s. The heart rate stayed in the 60s per minute. According to the protocol, a standard general anesthesia induction took place using commonly used anesthetic agents such as lidocaine, fentanyl, propofol, and succinylcholine. The patient was easy to mask ventilate, and an atraumatic intubation occurred, with a grade 2 view of the vocal cord. The patient's blood pressure after direct laryngoscopy was approximately 10 to 20 mm Hg higher than the initial measurements. Immediately after the intubation, the anesthesiologist placed a 20-gauge Arrow arterial line in the right radial artery as an invasive blood pressure monitoring line. Anesthetic agents approved by the protocol for this procedure were midazolam infusion at 0.1 to 0.4 mg/kg/h for amnesia, remifentanyl infusion at 0.1 to 0.3 µg/kg/min for analgesia, and 30% to 70% nitrous oxide.

General anesthesia was induced using an infusion of 4 mg/h of midazolam, an infusion of 0.05 µg/kg/min of remifentanyl, and 50% nitrous oxide. Shortly after the induction, the blood pressure decreased to 120/79 mm

Hg, with a heart rate of 69/min. Within the next 15 minutes, the blood pressure trended back to the patient's baseline and the heart rate stayed in the 60s per minute. The surgeon was notified of the critical high blood pressure. According to the Rheos treatment protocol, the patient's blood pressure should not be manipulated using any antihypertensive agents; therefore, no action took place. The patient's systolic blood pressure remained in the high 190s to 200s. Fentanyl boluses were given to buffer any pain stimulations upon incision that resulted in an increased blood pressure. Along with the fentanyl boluses, the anesthesia providers increased the remifentanyl infusion from 0.05 µg/kg/min to 0.2 µg/kg/min while the surgeon was implanting the Rheos device. The midazolam infusion was also titrated from 4 mg/h to 10 mg/h to ensure amnesia, as the anesthesia providers recognized that the Entropy device was reading 80 on the monitor. The surgeon successfully implanted the left carotid sinus lead to the patient's left carotid artery within 30 to 45 minutes after an incision was made.

The device testing began subsequently. A few minutes after the principal investigator sent an electrical stimulation from the pulse generator to the carotid sinus lead, which was attached to the patient's carotid artery, a slight decrease in the blood pressure was noted on the monitor. The systolic blood pressure trended downward from the 180s to 160s over 2 minutes via the arterial line. The surgeon decided to leave the carotid sinus lead on the left carotid artery over the next few weeks.<sup>17</sup> The surgeon believed that the left carotid sinus lead was adequate to manipulate the patient's blood pressure if it was indeed working.

The conclusion of the surgical procedure consisted of creating a pocket for the IPG and the subcutaneous tunneling for the lead bodies to allow connection of the system with the IPG. At this phase, preservation of the baroreflex function was no longer required. The anesthesia providers resumed conventional anesthetic techniques. The midazolam infusion was titrated off, and remifentanyl infusion was terminated after the administration of morphine for analgesia. The anesthesia providers weaned the patient off the mechanical ventilator and prepared for emergence. After the patient met the criteria for extubation, smooth emergence occurred without any complications. After achieving hemodynamic stability, the patient was transferred to the postanesthesia care unit.

## Discussion

Resistant hypertension is often difficult to treat, especially if the cause is unknown.<sup>1</sup> Alternative interventions such as diet modification, exercise, healthy lifestyle, and antihypertensive medications are the traditional treatments.<sup>1</sup> However, many patients often find themselves struggling with the prescribed diet, exercise regimen, or staying compliant with the antihypertensive medi-

cations.<sup>6</sup> In addition, the side effects, the maladaptive responses to these antihypertensive medications, and the contraindications to these medications may limit the combinations of traditional treatments.<sup>1</sup> The patient in this case study complained of having to take a large number of antihypertensive medications daily. Not only were they reportedly cumbersome, but they also interfered with her daily life and working hours. The patient frequently worried about forgetting to take her medications because of the amount of medications and each being on a different schedule. This patient is an example of the many patients with resistant hypertension who could potentially benefit from the Rheos therapy system.

The surgical implantation of the carotid sinus leads can be treated like any carotid endarterectomy procedures; however, the anesthetic management for this procedure is unique and challenging. Many anesthetic agents can potentially interfere with the testing of the Rheos system.<sup>6</sup> In addition to the anesthetic agents, antihypertensive and vasopressor medications that are routinely used during the intraoperative period can potentially alter the baroreceptors.<sup>5,6</sup> For that reason, their use was discouraged in this case.<sup>5,6</sup> They can be given after consulting with the surgeon performing the surgery, to ensure utmost safety to the patient.<sup>5,6</sup>

As an anesthesia provider, one should know that cardiovascular stability can be disrupted by the administration of anesthetic agents. The goal of the anesthetic management for implantation of the Rheos system is to preserve the carotid sinus baroreceptor sensitivity. This is accomplished by avoiding administering anesthetic agents that inhibit the baroreceptor reflex during electrode placement and the testing period.<sup>1,3-7</sup> Volatile anesthetics used to induce anesthesia, except for nitrous oxide, attenuate the baroreflex function in a dose-dependent manner.<sup>5,6</sup> For example, sevoflurane is tested to effectively block the carotid baroreflex, while isoflurane only blocks the response to electrical stimulations of the baroreflex in a dose-dependent fashion.<sup>4,5</sup> Increasing minimum alveolar anesthetic concentrations of these inhalational anesthetics can cause a progressive decrease in the baroreflex sensitivity and a reduction of blood pressure.<sup>5</sup> Therefore, anesthesia providers must also limit the administration of any volatile anesthetics that could induce hypotension.<sup>6</sup>

Nitrous oxide is one of the few anesthetic agents that has minimal effects on the carotid baroreflex system.<sup>6</sup> Nitrous oxide was proved scientifically to be the safe inhalation agent to use because it does not exhibit the same properties as other volatile agents.<sup>6</sup> The use of nitrous oxide is beneficial because it provides anesthesia and analgesia to the patients and allows the doses of barbiturate and benzodiazepine to be reduced.<sup>6</sup> In this case report, the anesthesia providers were able to decrease midazolam and remifentanyl dosages because nitrous oxide was used

as an adjunct anesthetic agent. This may have contributed to a quicker emergence of the patient from general anesthesia because longer-acting anesthetic agents required to maintain the patient's anesthesia were minimal.

In addition to avoiding volatile agents and antihypertensive medications, vasopressors must be used judiciously in patients with hypotension. However, a sufficient blood pressure is essential for the mapping of the carotid sinus. The device manufacturer, CVRx, Inc, suggested the use of intermittent boluses of ephedrine or continuous infusion of dopamine to support and stabilize a low blood pressure and to facilitate mapping.<sup>6</sup> Vasopressors, particularly  $\alpha$ -adrenergic agents, are minimized until baroreceptor mapping and electrode placement are completed.<sup>6</sup> The  $\alpha$ -adrenergic agents should be avoided, as they may cause more bradycardia that may compromise the mapping of the carotid sinus.<sup>6</sup> According to study protocol, all patients in the study should continue their preoperative therapy with  $\beta$ -blockers and aspirin, if receiving aspirin therapy preoperatively, to minimize potential risks of stroke or myocardial infarction.<sup>3,6,7</sup> However, this patient did not take any of her medications the day of surgery, which posed an increased risk of stroke and myocardial infarction. With this in mind, the anesthesia providers periodically alerted the surgeon of the patient's increasing blood pressure as the surgeon implanted the device into the patient's carotid sinus. The patient in this case study had a critically high blood pressure, but her heart rate consistently remained in the 60s per minute. There was no indication for any vasopressor. However, if intraoperative antihypertensive medications had been needed, there was a limited selection of antihypertensive medications that could be given without affecting the heart rate. Antihypertensive medications that were available at the author's facility were labetalol, esmolol, metoprolol, hydralazine, nitroglycerin, and nicardipine. Thus, frequent communication between the anesthesia providers and the surgeon is required to determine a desired level of blood pressure during the mapping of the carotid sinus.

A balanced anesthesia technique employing midazolam and remifentanyl is the most suitable for implantation of this device. Remifentanyl is the drug of choice for the Rheos trial because of its ultrashort-acting nature with a context-sensitive half-life of 4 to 5 minutes.<sup>6</sup> It has a similar anesthetic potency to fentanyl and has minimal direct cardiovascular depression.<sup>6</sup> Typically, a continuous IV infusion dose of 0.3 to 0.58  $\mu\text{g}/\text{kg}/\text{min}$  of remifentanyl titrated to effect is recommended.<sup>5</sup> A hypnotic agent such as etomidate and a neuromuscular blockade agent such as cisatracurium can be administered to facilitate endotracheal intubation. Other neuromuscular blockade agents, both depolarizing and nondepolarizing, may alter, although rarely and insignificantly, the systemic blood pressure and the heart rate.<sup>6,8</sup> However,

in this case, anesthesia providers used propofol and succinylcholine to facilitate endotracheal intubation with the approval of the surgeon and the study's principal investigator. As a result, there was a steep decrease from the 200s to 120s in the patient's systolic blood pressure following induction. The blood pressure gradually returned to baseline within 15 minutes before the testing phase of the Rheos device.

The use of propofol during the induction phase was allowed by the protocol, as approved by the CVRx investigator.<sup>6</sup> Dose- and concentration-dependent propofol is known to cause direct and profound cardiovascular depressant effects and decreased systemic vascular resistance effects.<sup>8,9(p342),10</sup> An induction dose of 2 to 2.5 mg/kg of propofol produces a 25% to 40% reduction of systolic blood pressure and an insignificant change in heart rate.<sup>10</sup> Propofol alters blood pressure by either resetting or inhibiting the baroreflex mechanism, as seen with a small increase in heart rate with a given decrease in arterial pressure, reducing the tachycardic response to hypotension.<sup>8,9(p342),10</sup> Propofol obtunds the baroreceptor activity<sup>3,8</sup>; however, if sufficient time were allowed for propofol residual effect to clear from the patient's body between induction and mapping, propofol can be used successfully without interfering with the result. The systolic blood pressure of the patient presented in this case study decreased substantially after the induction of propofol, from the 200s to 120s. The heart rate remained constant at approximately the 60s to 70s per minute, and this was attributed to the  $\beta$ -blocker that the patient had received previously. However, before the incision was made and the mapping took place, the patient's systolic blood pressure trended back to her baseline of 200s. Therefore, propofol can be ruled out as the culprit for any baroreflex interferences to the mapping at this point. The rapid metabolism and elimination of, or short duration of action of, propofol (within 10 minutes) makes the use of it feasible in a case like this.<sup>8,9(p342)</sup> In general, the initial induction of anesthesia is best performed with IV agents compared with inhalation agents, although propofol might not be the only choice.<sup>3</sup>

The 2 main challenges the anesthesia providers encountered during this case were the ability to maintain anesthesia depth and stability of the cardiovascular system. It was questionable whether the midazolam and remifentanyl infusions along with the nitrous oxide inhalational agent alone were adequate to keep the patient anesthetized. The Entropy (GE Healthcare, Waukesha, Wisconsin), a device used to monitor the anesthesia depth, registered a reading in the high 80s throughout the case when the anesthesia provider decided to increase the midazolam infusion rate. It was uncertain how reliable the Entropy was, but with patient safety and potential anesthesia awareness in mind, the midazolam infusion was increased.

The patient's extremely high blood pressure was another concern during this case. Despite the restriction that the patient's natural blood pressure must not be altered in order for the device to be successfully tested, this author believes that risks of stroke and ischemic cardiac events could not be disregarded. One study suggested the use of short-acting antihypertensive medications such as sodium nitroprusside, nitroglycerine, or esmolol to control hypertension preoperatively while the patient's own antihypertensive medications were being withheld.<sup>7</sup> This type of medication will prevent any cardiovascular accidents before the procedure, and because they are short-acting drugs, their effects will be eliminated by the time of device testing.<sup>7</sup> However, at this time, clearly stated proposals for when to intervene intraoperatively to avoid detrimental consequences of high blood pressure are nonexistent in the literature and the manufacturer's guidelines. The incidents of bradycardia can be pronounced. According to claims that were made on previous studies, some patients had experienced severe bradycardia episodes during exposure of the carotid bifurcation and mapping of the carotid sinus.<sup>6</sup> CVRx advises surgeons and anesthesia providers to carefully monitor for bradycardia as the carotid bifurcation is being manipulated.<sup>6</sup> The anesthesia provider should alert the surgeon if bradycardia occurs so the surgeon can cease any manipulations or stimulations to allow for spontaneous return of the heart rate without using any pharmacologic intervention.<sup>6</sup>

Another challenge for this case was the potential of recall or awareness using the total intravenous technique, as this type of anesthesia technique is of concern.<sup>6</sup> Other studies of the Rheos feasibility trial had reported subjective awareness during the procedure.<sup>3</sup> Entropy monitoring is recommended to monitor the level of sedation or anesthetic depth.<sup>6,9(pp684,1240-1241),11</sup> The target spectral Entropy reading is 40 to 60.<sup>6,9(pp684,1240),11</sup> The patient should be made aware preoperatively that the potential for recall is high. In this case, the patient did not recall any event during the intraoperative period when examined by the anesthesia providers postoperatively.

The use of nitrous oxide was permissible because CVRx has tested and found that nitrous oxide does not interfere with the baroreflex function.<sup>6</sup> CVRx also reports that nitrous oxide facilitates a quicker emergence from anesthesia, reduces postoperative nausea, and causes fewer sedative effects.<sup>6</sup> This belief conflicts with what most anesthesia textbooks support regarding postoperative nausea and vomiting (PONV).<sup>9(pp1397-1398),11</sup> The patient was prophylactically premedicated for PONV and did not have any episodes of PONV. Therefore, it is difficult to conclude whether nitrous oxide did not cause any nausea postoperatively, as claimed by CVRx.

The long-term outcome of this device is still in question. A limited number of past studies indicate a success-

ful and positive outcome in increased quality of life and risk reduction after the insertion of the Rheos system. However, in this case study, within a short time, the surgeon was not satisfied with the result. A decreasing trend in the patient's blood pressure took approximately 2 minutes, whereas a normal response should have been seen within 30 seconds.<sup>6</sup> The decrease in the blood pressure could also be related to the patient not being surgically stimulated during the testing period. When left alone during the surgery under anesthesia, the patient's blood pressure was 140s/70s.

Recent studies and clinical trials conducted by both CVRx and private parties prove the Rheos system device to be a successful new treatment of resistant hypertension. Illig et al<sup>3</sup> concluded in their trial that the implantable carotid sinus stimulator produces a statistically significant acute decrease in blood pressure (a reduction of 41 mm Hg in systolic blood pressure) without significant side effects. Most recent findings and reviews of literature also agree that the new treatment device appears safe and effective, and it may represent a useful adjunct to medical therapy in patients with resistant hypertension.<sup>7,12,13</sup> There were concerns in the literature regarding tissue ischemia and narcosis where the Rheos device is implanted causing more trauma or decreasing sensitivity of the device. These beliefs were refuted by Sanchez et al.<sup>14</sup> Data from a study by Sanchez et al<sup>14</sup> performed on sheep with a 6-month follow-up and on humans with a 3-month follow-up indicated that the implantation of the Rheos system is not associated with the development of carotid stenosis or injury. These data also support the concept of the lead placement and the need for longer-term investigation in larger multicenter prospective trials.<sup>14</sup>

Future considerations in giving anesthesia care for patients undergoing implantation of the Rheos system remain undetermined. A question remains regarding the patient's future surgeries, especially for a carotid endarterectomy. Whether the anesthesia providers can use conventional anesthesia treatment, or whether they must tailor their care because the patient's blood pressure system is now under the control of the Rheos device, remains concerning. Future research is recommended for the study of autoregulation in relation to cerebral perfusion after the implantation of the system as well as how the brain adjusts to the new changes in the blood pressure level. Another recommendation for future exploration is the use of the Rheos programmer to control the blood pressure intraoperatively by the anesthesia provider.

## Conclusion

The Rheos Baroreflex Hypertension Therapy System reduces the sympathetic outflow and increases the parasympathetic outflow via the activation of the carotid baroreflex. This system has been proved to be a success-

ful treatment of resistant hypertension through many studies conducted and sponsored by CVRx. However, the surgeon in this case study questioned the successfulness of the system. The successful implantation and mapping of the Rheos system is critically dependent on the selectivity and the administration of the anesthetic agents that minimally inhibit the carotid baroreceptor reflex. In other words, almost all of the anesthetic agents besides nitrous oxide, barbiturate, and benzodiazepine should be avoided because they produce sympathoinhibition effects, block the carotid baroreflex, and cause a dose-dependent reduction in the response to the electrical activation of the carotid baroreflex. Because of the restriction of some of the anesthetic agents that an anesthesia provider can use, this procedure poses major challenges to the anesthesia provider in planning for anesthesia care and managing risks to the patient. It is prudent for an anesthesia provider to be at all times vigilant to the patient's cardiovascular changes, anesthesia depth, and responses to the surgical stimulations. Major anesthesia considerations must be explored to facilitate safer anesthesia care to this patient population.

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