Pro-Con Debate: Are Patients With a Cardiovascular Implantable Electronic Device Suitable to Receive Care in a Free-Standing Ambulatory Surgery Center?

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Abstract: Migration of surgical and other procedures that require anesthesia care from a hospital to a free-standing ambulatory surgery center (ASC) continues to grow. Patients with cardiac implantable electronic devices (CIED) might benefit from receiving their care in a free-standing ASC setting. However, these patients have cardiovascular comorbidities that can elevate the risk of major adverse cardiovascular events. CIEDs are also complex devices and perioperative management varies between devices marketed by various manufacturers and require consultation and ancillary services, which may not be available in a free-standing ASC. Thus, perioperative care of these patients can be challenging. Therefore, the suitability of this patient population in a free-standing ASC remains highly controversial. Although applicable advisories exist, considerable discussion continues with surgeons and other proceduralists about the concerns of anesthesiologists. In this Pro-Con commentary article, we discuss the arguments for and against scheduling a patient with a CIED in a free-standing ASC.

GLOSSARY

ASA = American Society of Anesthesiologists; **ASC** = ambulatory surgery center; **CIED** = cardiac implantable electronic device; **CRT** = cardiac resynchronization therapy; **CRT-P** = cardiac resynchronization therapy-pacemaker; **CRT-D** = cardiac resynchronization therapy-defibrillator; **ECG** = electrocardiogram; **EMI** = electromagnetic interference; **ICD** = implantable cardioverter-defibrillator; **LVEF** = left ventricular ejection fraction; **MRI** = magnetic resonance imaging; **S-ICD** = subcutaneous implantable cardioverter-defibrillator

Medically complex patients are increasingly being scheduled in free-standing ambulatory surgery centers (ASCs), making patient selection critical, as it can impact patient safety, perioperative outcomes, and efficiency.[1] A cardiac implantable electronic device (CIED) has traditionally referred to an implanted transvenous pacemaker or implantable cardioverter-defibrillator (ICD), but several novel devices have recently been introduced (Table 1).[2–4] It is estimated that more than 250,000 CIEDs are implanted annually in the United States[3,5,6] making it inevitable that anesthesiologists practicing in a free-standing ASC will need to determine if patients with a CIED are suitable for ambulatory procedures. Although there are existing applicable advisories,[7,8] considerable discussion continues with surgeons and other proceduralists regarding the concerns of anesthesiologists. Therefore, the suitability of this patient population in a free-standing ASC remains controversial. In this Pro-Con commentary article, we discuss the arguments and evidence for and against scheduling a patient with a CIED in a free-standing ASC.

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PROS OF AN ASC SETTING FOR A PATIENT WITH A CIED

Preoperative Considerations

It is argued that patients with a CIED have a high cardiac comorbidity burden,[9–11] which can potentially increase perioperative cardiac morbidity. However, patients are scheduled for procedures in a free-standing ASC only if comorbid conditions are stabilized and optimized (ie, patients have an American Society

Table 1. Types and Characteristics of Cardiac Implantable Electronic Devices

Device characteristic	Transvenous pacemaker	Transvenous ICD	S-ICD	CRT	Leadless pacemaker
Leads	Single or multiple (atrial, ventricular)	Multiple (right atrial, right ventricular). Shock coils present	Single subcutaneous lead	Multiple (right atrial, right ventricle, coronary sinus)	No leads, device implanted in the right ventricle
Pacing capability	Yes	Yes	No	Yes	Yes
Antitachyarrhythmia capability	No	Antitachycardia pacing and/or defibrillation	Defibrillation only	CRT-P: no CRT-D: yes	No
Rate modulation capability	Variable	Variable	No	Yes	Yes
Typical magnet response	Converts to asynchronous pacing	Suspends antitachyarrhythmia therapy; no change to pacing therapy	Shock therapy is inhibited	CRT-P: converts to asynchronous pacing; CRT-D: suspends antitachyarrhythmia therapy with no change to pacing therapy	Micra: no response Nanostim: converts to asynchronous pacing

Abbreviations: CRT, cardiac resynchronization therapy; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; ICD, implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator.

of Anesthesiologists [ASA] physical status of ≤III). Nevertheless, it is imperative that these patients are referred for timely preoperative evaluation before the day of surgery. This will also allow time for the anesthesiologist to obtain device information from the patient's medical records. Alternatively, the device identification card can be used to obtain information from the manufacturer's website or calling the "help line." These resources can also be used to obtain advice regarding specific perioperative management, such as the need for preoperative programming and response to magnet placement.[12]

Adequate functioning of the CIED must be confirmed before surgery.[8] It is recommended that CIEDs, particularly ICDs, should be interrogated within 30 days before the surgical procedure.[13] Adequacy of device function can be evaluated by reviewing a recent interrogation report or cardiologist's notes. Interrogation reports provide basic information about the indication for implantation, battery life, last programmed date, potential magnet responses, magnet rate, percentage paced events, number of ventricular tachyarrhythmia events, and number of shocks delivered.[14,15]

Remote monitoring now plays a central role in the management of patients with CIEDs and is capable of daily transmission of stored CIED information from the device to the health care provider.[16–19] Remote interrogation, combined with virtual cardiologist consultation via telemedicine, is increasingly utilized and allows for early identification and management of any potential issues with the device. Thus, the patient does not need to schedule a cardiology office visit for CIED interrogation.[20] With an ICD, the application of a magnet would result in suspension of the antitachyarrhythmia function but not conversion to asynchronous mode. Therefore, in patients with pacemaker dependence, preoperatively programming the device may be necessary,[3,13,21,22] which may also be facilitated through remote consultation and programming. Pacemaker dependence can be determined based on the indication for CIED placement (eg, history of atrioventricular node ablation and significant ventricular bradyarrhythmias causing syncope) or by a paced rhythm on the electrocardiogram (ECG).[22] Pacemaker-dependent patients may be suitable candidates for procedures in a free-standing ASC as long as adequate precautions are taken to prevent the adverse effects of electromagnetic interference (EMI). For example, pacing-dependent patients who have well-controlled comorbidities and are scheduled for procedures with no use of electrocautery (eg, cataract surgery) or procedures below the umbilicus and with CIEDs that are simple transvenous pacemakers can be good candidates for a free-standing ASC.

Intraoperative Considerations

There is a concern of device malfunction from EMI generated during the procedure. However, modern CIEDs are robust and resistant to EMI, so much so that some are even magnetic resonance imaging (MRI) compatible. In addition, more than half of all procedures performed in the ambulatory setting have a low risk of EMI generation.[23–26] About 40% of outpatient procedures are interventions that do not require the use of electrocautery, including cataract surgery and other ophthalmic procedures, gastrointestinal endoscopic procedures, diagnostic bronchoscopy, diagnostic cystoscopy, and analgesic procedures for treatment of chronic pain (eg, nerve, joint, and neuraxial injections). At least an additional 15% of outpatient procedures are located below the umbilicus, or at least 6 inches (15 cm) from the CIED generator and leads, which are therefore at low risk of EMI. Examples include inguinal hernia repair, urogenital procedures, and orthopedic procedures in the lower extremities like bunionectomy and knee arthroscopy or arthroplasty. These types of procedures can be safely performed in an ambulatory outpatient setting

even if monopolar electrocautery or radiofrequency ablation is used.[27,28] In many other procedures, bipolar electrocautery or an ultrasound (harmonic) scalpel can be used to minimize the risk of EMI. EMI generation can be reduced by (a) placing the grounding pad of the electrocautery system as close to the surgical site as possible such that the current flow does not intersect the CIED generator or leads and (b) setting the monopolar electrocautery to the lowest feasible energy level and using short, irregular, intermittent bursts.[13]

Postoperative Considerations

It is suggested that free-standing ASC efficiency may be reduced because of delayed discharge due to the need for postoperative device assessment and programming. If the CIED was programmed before surgery or a magnet used intraoperatively, the device must be interrogated to ensure proper functioning and reprogrammed if necessary. This usually takes only a few minutes and should not delay patient discharge. Careful preoperative planning and coordination should allow timely presence of a member of the CIED team in the free-standing ASC. In some cases, remote monitoring and interrogation, as well as a virtual cardiologist consultation, should facilitate postoperative and postdischarge care.

Overall, the above discussion supports that the free-standing ASC setting is safe for appropriately selected CIED patients with good ventricular function (ASA physical status of ≤III), as well as applying precautions to reduce EMI and providing appropriate postoperative care. Many of the arguments posed for avoiding the free-standing ASC setting for patients with CIED rely on outdated information and concerns that are not valid in modern clinical practice.

CONS OF AN ASC SETTING FOR A PATIENT WITH A CIED

Preoperative Considerations

CIED implantation suggests that a patient has a high cardiac comorbidity burden, which may not be fully realized preoperatively, as preoperative evaluation is typically performed on the day of the procedure. Even if cardiac comorbidities are optimized before the procedure, patients may be frail after survival from a serious arrhythmia or sudden cardiac arrest due to advanced cardiac disease, such as cardiomyopathy, neuromuscular disorders associated with heart disease, prolonged-QT syndrome, or Brugada syndrome.[13,18,20] This group of patients may have a left ventricle ejection fraction (LVEF) of <35% or New York Heart Association class >II. They are usually categorized with an ASA physical status of IV, and they are thus not suitable for a procedure in a free-standing ASC.[1] Due to inadequate support and lack of personnel, a free-standing ASC may not be equipped to manage the potential perioperative complications, such as unanticipated cardiac arrhythmia and hemodynamic compromise. Consultation and ancillary services may not be readily available.

Another issue is that CIED technology is advancing rapidly with increasing complexity and inconsistency in the capability of delivering pacing or antitachycardia therapy. For example, cardiac resynchronization therapy (CRT) devices may or may not have defibrillation or antitachycardia functions,[29] while leadless intracardiac pacemakers have pacemaker and rate modulation capabilities but are not capable of delivering tachyarrhythmia therapies (Table 1). Furthermore, the response to magnets and the requirements for reprogramming vary between manufacturers. For example, the subcutaneous (S)-ICD lacks permanent pacing for bradycardia or antitachycardia pacing capabilities.[30,31] An S-ICD has a wider sensing region and, hence, is more prone to malfunction due to EMI. Therefore, although magnet application will suspend ventricular tachyarrhythmia therapy, it is recommended that an S-ICD, which are implanted in patients without a current or anticipated need for pacing,[32,33] be reprogrammed preoperatively to "therapy off" mode.[34]

CRT devices synchronize contraction of the right and left ventricles and thus improve electromechanical coupling in heart failure patients with LVEF ≤35%[35,36] and may have an ICD component (cardiac resynchronization therapy-defibrillator [CRT-D]) or only the biventricular pacing components (cardiac resynchronization therapy-pacemaker [CRT-P).[29] For CRT-D, the antiarrhythmic therapy function should be suspended during procedures with high risk for EMI by reprogramming or using a magnet. In both scenarios, the resynchronization capability will not be suspended. In contrast, placing a magnet on a CRT-P device will make it pace in asynchronous mode.[37] Given that CRT systems are commonly used in patients with decreased ventricular function, converting to asynchronous mode may have unpredictable hemodynamic effects.[35]

Leadless intracardiac pacemakers are small CIEDs implanted in the right ventricle with single-chamber ventricular pacemaker and rate modulation capabilities.[38] Two devices are currently available. The Micra Trans catheter Pacemaker System (Medtronic) is MRI compatible but does not have a magnet sensor, and therefore, it does not convert to asynchronous mode in response to magnet application.[39] The Nanostim leadless intracardiac pacemaker (St. Jude Medical) is similar to the Micra device but has the advantage of magnet responsiveness, consisting of pacing at 90 beats per minute in asynchronous mode.[40,41] Neither of

these devices are capable of delivering tachyarrhythmia therapies. The Micra device does not respond to the application of a magnet, and thus, pacing-dependent patients require specific software for reprogramming, which necessitates technical support.[42]

Intraoperative Considerations

Even during minimally invasive procedures. the risk from EMI generation exists (Table 2).[43–46] If significant intraprocedural EMI is anticipated and unavoidable, the anesthesiologist at a free-standing ASC should be prepared to place the CIED in asynchronous mode and/or suspend its antitachyarrhythmia functions. This can be achieved with the use of magnets or by reprogramming of the device; however, the choice remains highly controversial.[47] Although use of a magnet has been suggested as an option, it involves several challenges. First, the anesthesia provider needs to be sure that the device is not programmed to ignore the magnet effect (mode "off").[14,15] Second, some devices do not provide a signal (beeping tones) to confirm that antitachyarrhythmia therapy has been disabled. Third, the magnet needs to be reliably secured over the CIED generator, easily accessible to the provider, and not interfere with the surgical field.

Of note, about 85% of pacemakers implanted in the United States are programmed for rate modulation, which may represent a challenge for anesthesiologists, as these devices may increase the pacing rate inappropriately in response to EMI or mechanical hyperventilation. Finally, for patients who are pacemaker-dependent and with certain type of devices, reprogramming is necessary because with most ICDs the magnet will deactivate the antitachyarrhythmia functions but will not affect the pacing mode.[3,8,21,22] Reprogramming the CIED before the procedure requires the intervention of a CIED team, which may not be logistically feasible in a free-standing ASC. Also, it may delay surgery start and reduce free-standing ASC efficiency.

Table 2. Procedures With High Electromagnetic Interference Risk

Procedures between the mandible and the xiphoid or operations involving the neck, shoulders, or upper thorax
Operations performed close to the cardiovascular implantable electronic device generator or leads
Radiofrequency ablation for lesions located above the umbilicus
Lithotripsy procedures
Interventional pulmonary procedures using monopolar electrocautery, argon plasma coagulation, or electromagnetic navigational bronchoscopy
Diagnostic or interventional procedures using MRI
Transcutaneous electrical nerve stimulation
Electroconvulsive therapy.

Abbreviation: MRI, magnetic resonance imaging.

Postoperative Considerations

In the postoperative period, patients need to be closely monitored until the CIED is reprogrammed and interrogated. This requires technical support from a cardiologist or CIED team. Thus, there is potential for delay in not only the procedure start but also discharge home, which can decrease free-standing ASC efficiency.[48]

Given these considerations, patients with CIEDs should not be scheduled for procedures in a free-standing ASC unless (a) the patient's comorbid conditions are optimized; (b) the desired procedure does not involve the risk of EMI; (c) the anesthesiologist is aware of the functional capabilities of the specific device, including magnet response, rate modulation, and the ability to provide permanent pacing or antitachyarrhythmia therapy; and (d) CIED team support is readily available preoperatively and postoperatively, if needed.

CONCLUSIONS

This Pro-Con debate suggests that the approach to the patient with a CIED should be individualized. Caution should be exercised, as not all patients with CIED are suitable for a free-standing ASC. Before scheduling in a free-standing ASC, a patient with a CIED should undergo preoperative evaluation and optimization of comorbid conditions (ASA physical status ≤III). In addition, it is necessary to evaluate CIED function, including battery life and appropriateness of magnet use. Possible intraoperative EMI generation should also be determined. Patients with well-controlled comorbidities scheduled for low-risk procedures with no risk of EMI (eg, cataract surgery under locoregional anesthesia) are in general suitable for a free-standing ASC, regardless the type of CIED.[49] For other patients, free-standing ASC suitability should be determined on a case-by-case basis, recognizing the limitations of individual free-standing ASC. The ambulatory facility should be properly prepared with the necessary equipment and personnel to manage unforeseen events. Some patients may need prophylactic placement of transcutaneous pacing/defibrillation pads (eg, Zoll AED pads; Zoll Medical Corporation) and should be scheduled in a free-standing ASC with caution. Those include pacing-dependent patients with a transvenous pacemaker or ICD having procedures where magnet application may interfere with the surgical field, or the magnet cannot be reliably secured over the CIED generator; high cardiac risk patients with an ICD undergoing procedures with high risk for EMI; high-risk patients undergoing procedures in position that would prevent placement external pads; and pacing-dependent patient with concomitant S-ICD and a pacemaker.[50] Efforts must be made to

Table 3. Patients With a CIED Not Suitable to Receive Care in a Free-Standing Ambulatory Surgery Center

Patients with American Society of Anesthesiologists physical status ≥IV
Patients with comorbidities that are not optimized
CIED implanted within 3 mo before the procedure
Patients who have experienced recurrent implantable cardioverter-defibrillator shocks despite optimal device programming and appropriate medical therapy
Cardiac resynchronization therapy devices implanted to improve electromechanical coupling in a patient with left ventricle ejection fraction ≤35%
Free-standing ambulatory surgery centers that do not have access to CIED team to reprogram the device preoperatively and postoperatively, when necessary.
Patients with a complex CIED undergoing procedures requiring electromagnetic interference (Table 2)
Patient's anesthesia provider is unaware of the functional capabilities of the CIED

Abbreviation: CIED, cardiac implantable electronic device.

reduce EMI by using bipolar electrocautery or an ultrasound (harmonic) scalpel. If monopolar electrocautery is necessary, the grounding pad of the electrocautery system should be placed as close to the surgical site as possible, such that the current flow does not intersect the CIED generator or leads, and the lowest feasible energy level should be used. There must be access to timely technical support from a CIED team for consultation, particularly if preoperative and postoperative programming is deemed necessary. If the device was programmed preoperatively, exposed to EMI, or magnet was used, adequate CIED function should be confirmed before discharge home, which can be done remotely. Patients with CIED not suitable for a free-standing ASC are presented in Table 3. Further high-impact research is needed to confirm the safety and benefits of using a free-standing ASC for procedures in patients with a modern CIED. This would include the number of free-standing ASCs that have access to sophisticated CIED assessment.

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