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EDITORIAL COMMENT

Combining Leadless Pacemaker With a Subcutaneous Implantable Cardioverter-Defibrillator

With Self-Discipline Most Anything Is Possible*

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The subcutaneous implantable cardioverter-defibrillator (S-ICD) and leadless pacemaker (LP) have been proven to be safe and effective alternatives to conventional transvenous devices,[1-3] and they have the unique advantage of not requiring intracardiac leads. However, patients who require both an ICD and pacing therapy have not been considered eligible for these devices, because the S-ICD lacks pacing capabilities, and the current generation of LPs is not integrated with an ICD. The combination of an S-ICD and LP would be particularly beneficial for specific subsets of patients, such as those with limited venous access options or with recurrent device infections.[4,5] The feasibility of combining the S-ICD with an LP has been previously documented in isolated case reports[6-8] and tested in preclinical studies.[9] When combining an S-ICD with an LP, it is crucial to ensure a lack of interference between the LP and the sensing/defibrillation therapy of the S-ICD.[9] In this issue of the *JACC: Case Reports*, 2 independent reports describe the successful simultaneous implantation of an S-ICD and an LP in patients with congenital heart disease (CHD) and limited venous access or recurrent device-related infections.[10,11]

Nieves et al[10] describe their institutional workflow to simultaneous implantation of an S-ICD and an LP in 2 patients with recurrent device-related infections. The first step of this approach was insertion of the LP and, following the initial LP deployment, the paced QRS morphology was screened intraoperatively for compatibility with the S-ICD. This was performed by applying electrode stickers on the both right and left sides of the sternum to guide the optimal positioning of the S-ICD lead. Of note, intraoperative S-ICD screening failed in 1 patient, and this prompted LP recapture and redeployment to another location. Once a satisfactory LP position was achieved with successful S-ICD screening, the LP was released and the S-ICD lead implanted in the right or left parasternal location as directed by the screening results. In 1 patient, a permanent left ventricular assist device was present, and the investigators chose to use the alternate vector for S-ICD sensing to minimize the risk of oversensing from left ventricular assist device electromagnetic interference.[12] At the end of the procedure, ventricular fibrillation was induced, and the investigators verified in real time proper ventricular fibrillation sensing from both the LP and S-ICD as well as adequate defibrillation safety margin. The report by Nieves et al[10] provides clinically important insights into how to ensure the proper combined function of these devices, and it is a must read for physicians who are considering the combined implantation of an S-ICD and LP in their patients.

In a separate contribution, Takami et al[13] describe the successful combined use of an S-ICD and LP in a patient with Ebstein's anomaly, prior tricuspid valve replacement, and bidirectional Glenn surgical repair. This report is of clinical interest in light of the limited vascular access options frequently encountered in

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CHD patients. In this regard, there are several CHD scenarios where a transvenous approach to lead implantation is challenging or associated with substantial risk:

1. Patients with an intracardiac shunt who are at higher risk of thromboembolic events. In these patients, it is either recommended that the shunt be closed before the lead implantation procedure or that the use of transvenous leads be avoided.[14]
2. Patients with transposition of the great arteries who have coronary sinus abnormalities or venous baffle obstruction. In these patients, careful preprocedural planning is needed to evaluate the venous access options and the feasibility of transvenous lead implantation.[5]
3. Patients with a single ventricle morphology and Fontan circulation who have their systemic venous circulation directly routed to the pulmonary arteries and, therefore, have no venous access to the heart. Transvenous lead implantation has been shown to be feasible with direct puncture from the pulmonary artery to the atria, but this increases the risk of thromboembolic events.[15] Patients with Ebstein's anomaly who have their superior vena cava connected to the pulmonary artery, like in the case described by Takami et al,[13] also fall in the same category. However, this group still maintains access to the heart through the inferior vena cava, which makes LP implantation feasible.
4. Congenital absence of the superior vena cava and interrupted inferior vena cava. Although these occur less frequently in the general population, patients with CHD have a higher prevalence of these abnormalities.[11]

In these scenarios, the possibility of simultaneously implanting an S-ICD and an LP (assuming the feasibility of transfemoral venous access to the right ventricle) would be an appealing option when there is an indication for both an ICD and pacing therapy. In conclusion, the 2 contributions published in this issue of the *JACC: Case Reports* support a role for the combined implantation of an S-ICD and an LP in patients who are not good candidates for conventional transvenous leads.[10,13] The procedural workflow described in these reports was associated with excellent acute and short-term postprocedural outcomes. (Follow-up ranged from 3 to 18 months.) Although these outcomes are promising, further investigations are needed to establish the long-term performance and safety of combining an S-ICD with an LP.

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REFERENCES

1. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. Subcutaneous or transvenous defibrillator Therapy. *N Engl J Med*. 2020;383:526–536.

2. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. *Eur Heart J*. 2014;35:1657–1665.

3. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. *N Engl J Med*. 2015;373:1125–1135.

4. Oginosawa Y, Abe H, Nakashima Y. The incidence and risk factors for venous obstruction after implantation of transvenous pacing leads. *Pacing Clin Electrophysiol*. 2002;25:1605–1611.

5. Ruckdeschel ES, Quaife R, Lewkowiez L, et al. Preprocedural imaging in patients with transposition of the great arteries facilitates placement of cardiac resynchronization therapy leads. *Pacing Clin Electrophysiol*. 2014;37:546–553.

6. Mondesert B, Dubuc M, Khairy P, Guerra PG, Gosselin G, Thibault B. Combination of a leadless pacemaker and subcutaneous defibrillator: first in-human report. *Heart Rhythm Case Rep*. 2015;1:469–471.

7. Ljungstrom E, Brandt J, Mortsell D, Borgquist R, Wang L. Combination of a leadless pacemaker and subcutaneous defibrillator with nine effective shock treatments during follow-up of 18months. *J Electrocardiol*. 2019;56:1–3.

8. Ito R, Kondo Y, Winter J, et al. Combination of a leadless pacemaker and subcutaneous implantable cardioverter defibrillator therapy for a Japanese patient with prosthetic valve endocarditis. *J Arrhythm*. 2019;35:311–313.

9. Tjong FV, Brouwer TF, Smeding L, et al. Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance. *Europace*. 2016;18:1740–1747.

10. Nieves J, Laslett DB, Basil A, Whitman IR, Cooper JM, Cronin EM. Simultaneous leadless pacemaker and subcutaneous ICD implantation with intra-operative screening: workflow in two patients. *J Am Coll Cardiol Case Rep*. 2022;4(23):101535.

11. Cordina RL, Celermajer DS, McGuire MA. Systemic venous anatomy in congenital heart disease: implications for electrophysiologic testing and catheter ablation. *J Interv Card Electrophysiol*. 2012;33:143–149.

12. Black-Maier E, Lewis RK, Barnett AS, et al. Subcutaneous implantable cardioverter-defibrillator troubleshooting in patients with a left ventricular assist device: a case series and systematic review. *Heart Rhythm*. 2020;17:1536–1544.

13. Takami M, Fukuzawa K, Kiuchi K, Matsumoto K, Izawa Y, Hirata K. Treatment strategy for fatal arrhythmias in Ebstein's anomaly combined with leadless pacemaker and S-ICD implantations. *J Am Coll Cardiol Case Rep*. 2022;4(23):101464.

14. Hernandez-Madrid A, Paul T, Abrams D, et al. Arrhythmias in congenital heart disease: a position paper of the European Heart Rhythm Association (EHRA), Association for European Paediatric and Congenital Cardiology (AEPC), and the European Society of Cardiology (ESC) Working Group on Grown-Up Congenital Heart Disease, endorsed by HRS, PACES, APHRS, and SOLAECE. *Europace*. 2018;20:1719-1753.

15. Arif S, Clift PF, De Giovanni JV. Permanent trans-venous pacing in an extra-cardiac Fontan circulation. *Europace*. 2016;18:304-307.

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