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Editorial comment

Subcutaneous ICD in pediatric patients: safety matches necessity

DAI subcutáneo en pacientes pediátricos: una herramienta tan segura como necesaria

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Implantable cardioverter-defibrillators (ICDs) play a key role in preventing sudden cardiac death across a wide spectrum of heart diseases. Their efficacy is supported by clinical trials of transvenous (TV) devices in adult patients.[1] TV-ICDs, however, carry numerous risks, mostly related to the presence of a lead in direct contact with the heart and bloodstream. Complications with the strongest prognostic impact are pneumothorax, cardiac perforation, lead malfunction, device-related infections, and inappropriate shocks. In recent years, extravascular ICDs have been designed to overcome the drawbacks of conventional systems. The first extravascular systems to appear on the market were subcutaneous ICDs (S-ICDs). These ICDs have proven to be both safe and effective therapy in detecting and delivering cardioversion/defibrillation shocks to malignant ventricular arrhythmias in patients not requiring antibradycardia or antitachycardia pacing or cardiac resynchronization therapy.[2,3] S-ICDs are thus a very attractive alternative for pediatric patients, who are particularly prone to intravascular lead complications.

In a recent article published in *Revista Española de Cardiología*, Centeno et al.[4] compare the safety of S-ICDs and TV-ICDs in children and adolescents at a hospital renowned for pediatric heart care. After a median follow-up of 3.7 years, the authors found no significant differences in the composite endpoint of acute and chronic complications and inappropriate shocks between 26 patients who had received an S-ICD (event-free survival of 92% at 1 year and 80% at 5 years) and 19 patients who had received a TV-ICD (event-free survival of 73% at 1 year and 63% at 5 years). At 5 years, however, patients who had undergone S-ICD implantation had fewer complications than T-ICD carriers (complication-free survival rate of 96% vs 57%, $P = .016$) and a similar rate of inappropriate shocks (inappropriate shock-free survival of 85% vs 89%, $P = .86$). The authors also observed a lower risk of complications in S-ICD carriers with a lower body weight (body mass index [BMI] $\leq 20\ kg/m^2$) (complication-free survival rate of 100% vs 48% for TV-ICD carriers, $P = .04$).

Pediatric TV-ICD placement is technically challenging, not only because the devices are designed for adults, but also because there may be anatomic obstacles to overcome (eg, in children with congenital heart defects). While S-ICDs eliminate the risks associated with intravascular placement, they require a larger generator, which poses a challenge in lower-weight patients. The PRAETORIAN trial, the largest randomized controlled trial to compare the safety of S-ICDs and TV-ICDs in adults, found similar rates of short- and mid-term complications.[3] Centeno et al.[4] reported similar findings for children and adolescents, although the results for S-ICDs might have been even more favorable had there not been 2 cases of premature battery depletion in this group.

Several noteworthy findings emerged from the work of Centeno et al.[4] First, most implant procedures were performed in the electrophysiology laboratory, highlighting the safety of this environment for pediatric ICD placements. Second, the possibility of placing S-ICD leads in a parasternal position in pediatric patients is reassuring, as it minimizes the number of incisions required without interfering with pacing or defibrillation. A factor very likely contributing to successful parasternal positioning was fluoroscopic guidance (with minimum exposure times). The third finding of note is the possibility of subserratus positioning in low-weight patients.

Contrasting with observations in adults,[3,5,6] the 3 infections that occurred in the pediatric series published by Centeno et al.[4] were all associated with S-ICDs.[4] It would have been interesting to know whether these infections were associated with factors such as generator position (intermuscular or submuscular), lead placement (left or right parasternal region), or even learning curve effects. Nonetheless, it is promising that all the infections resolved without the need for device removal and that there were no fatal outcomes.

Optimal timing of TV-ICD implantation in a child who has not yet reached physical maturity is very complicated. In the series reported by Centeno et al.,[4] all the patients who developed complications due to lead stretching had undergone TV-ICD implantation. TV-ICD carriers, however, were slightly younger than S-ICD carriers. They were also shorter and lighter, although the differences in BMI were not significant. S-ICDs probably allow for lead slack, as evidenced by the absence of complications in patients with a height increase of up to 10 cm.

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One of the main findings in the study published by Centeno et al.[4] is the similar incidence of inappropriate shocks in the S-ICD and TV-ICD groups. Inappropriate shock-free survival at 1, 3, and 5 years was 96%, 85%, and 85% respectively in the S-ICD group and 89% at all 3 time points in the TV-ICD group. Three patients from each group (12% of those in the SC-ICD group and 16% of those in the TV-ICD group) received inappropriate shocks. This relatively low incidence is similar to or slightly lower than that reported in other recent pediatric series.[7–10] As shown by previous studies,[11,12] the low frequency of inappropriate shocks can be explained by the programming of high detection rates for both devices (ventricular fibrillation [VF] zone $>$ 250 bpm for S-ICDs and $>$ 220 bpm for TV-ICDs) and, in the case of S-ICDs, use of a conditional zone $>$ 220 bpm and a SMART Pass filter (Boston Scientific, USA). Inappropriate shocks were caused by T-wave oversensing and myopotentials in the S-ICD group and T-wave oversensing, sinus tachycardia, and atrial flutter in the TV-ICD group. There were no inappropriate shocks due to supraventricular arrhythmias in the S-ICD group. Programming of a second therapy zone of 190 to 220 bpm in some TV-ICD carriers may have led to inappropriate shocks due to sinus tachycardia or atrial flutter.

The incidence of appropriate shocks delivered by S-ICDs and TV-ICDs was also similar. In this case, respective appropriate shock-free survival rates at 1, 3, and 5 years were 88%, 62%, and 54% in the S-ICD group and 94%, 88%, and 77% in the TV-ICD group. Nine (35%) of the 26 patients with an S-ICD received appropriate shocks. This incidence is higher than rates reported in the literature and is probably the result of a judicious assessment of indications.[7,8] The first shock was effective in all cases. Appropriate shocks were due to polymorphic ventricular tachycardia or VF in 7 patients (27%) and sustained monomorphic ventricular tachycardia (SMVT) in 2 (7.7%). Four patients in the TV-ICD group (21%) received appropriate shocks, which were due to SMVT in 2 patients and polymorphic ventricular tachycardia or VF in the other 2. Again, the first shock was effective in all cases. Although statistical comparisons are limited by the small sample sizes, the higher number of SMVTs in the TV-ICD group could be related to the higher incidence of dilated cardiomyopathy compared with hypertrophic cardiomyopathy.

Although an increasing number of publications support the use of S-ICDs in pediatric patients, many of them have analyzed young adults with congenital heart defects.[13] Large series with long-term follow-up are needed to obtain more information on experience with S-ICDs in pediatric patients, who are a particularly vulnerable population. Despite its modest sample size (45 patients), the study by Centeno et al.[4] is one of the first to provide evidence showing the safety of S-ICDs in an exclusively pediatric population. It should not be forgotten that all the patients were younger than 18 years.

Another strength and novel aspect of the study by Centeno et al.[4] is that, unlike previous studies,[7–9,13] it compared TV-ICDs and S-ICDs in 2 groups that were well balanced, particularly with respect to age, BMI, and underlying diseases. Their findings therefore clearly show that S-ICDs can safely and effectively prevent sudden cardiac death in children.

The work of Centeno et al.[4] is also distinguished from previous studies by its inclusion of a not insignificant percentage of patients with a BMI $\leq$ 20 (46% of S-ICD carriers and 58% of TV-ICD carriers). This significant representation is important, as low weight has been traditionally associated with a larger number of complications, particularly more implant-related complications. This association was not observed in the study published by Centeno et al.

The study had a relatively small sample, precluding the ability to draw firmer conclusions on the use of S-ICDs in pediatric patients. Furthermore, although the follow-up period was longer than that of other series,[8,9] it was still relatively short (median of 3.71 years in the S-ICD group and 5.50 years in the TV-ICD group), precluding analysis of long-term complications.

We would like to end by commending the authors, not only for investigating the use of S-ICDs in a little-studied population, but also for providing further evidence that these devices are a safe and effective option for preventing sudden cardiac death.

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REFERENCES

1. Zeppenfeld K, Tfelt-Hansen J, de Riva M, et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Eur Heart J.* 2022;43:3997–4126.
2. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med.* 2010;363:36–44.
3. Knops RE, Olde Nordkamp LRA, Delnoy P-PHM. et al. Subcutaneous or Transvenous Defibrillator Therapy. *N Engl J Med.* 2020;383:526–536.
4. Centeno M, García-Rovés R, Pérez-Caballero R, et al. Complications and inappropriate shocks in pediatric patients receiving a subcutaneous implantable cardioverter defibrillator. *Rev Esp Cardiol.* 2023. http://dx.doi.org/10.1016/j.rec.2023.08.014.
5. Gold MR, Lambiase PD, El-Chami MF, et al. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial. *Circulation.* 2021;143:7–17.
6. Boersma L, Barr C, Knops R, et al. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. *J Am Coll Cardiol.* 2017;70:830–841.
7. Krause U, Müller MJ, Wilberg Y, et al. Transvenous and non-transvenous implantable cardioverter-defibrillators in children, adolescents, and adults with congenital heart disease: who is at risk for appropriate and inappropriate shocks? *Europace.* 2019;21:106–113.
8. Silvetti MS, Bruyndonckx L, Maltret A, et al. The SIDECAR project: S-IcD registry in European paediatriC and young Adult patients with congenital heaRt defects. *Europace.* 2023;25:460–468.
9. von Alvensleben JC, Dechert B, Bradley DJ, et al. Subcutaneous Implantable Cardioverter-Defibrillators in Pediatrics and Congenital Heart Disease: A Pediatric and Congenital Electrophysiology Society Multicenter Review. *JACC Clin Electrophysiol.* 2020;6:1752–1761.
10. Mori H, Sumitomo N, Tsutsui K, et al. Efficacy of SubcutAneous implantable cardioVErter-defibrillators in $\leq$18 year-old CHILDREN: SAVE-CHILDREN registry. *Int J Cardiol.* 2023;371:204–210.
11. Moss AJ, Schuger C, Beck CA, et al. Reduction in inappropriate therapy and mortality through ICD programming. *N Engl J Med.* 2012;367:2275–2283.
12. Theuns DAMJ, Brouwer TF, Jones PW, et al. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm.* 2018;15:1515–1522.
13. Quast ABE, Brouwer TF, Kooiman KM, et al. Comparison of complications and shocks in paediatric and young transvenous and subcutaneous implantable cardioverter-defibrillator patients. *Netherlands Hear J Mon J Netherlands.* 2018;26:612–619.