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EDITORIAL COMMENT

Zero-Fluoroscopy Pacemaker Implantation

A Bridge Too Far?*

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Every year, a sizable number of patients are implanted with a cardiac implantable electronic device (CIED), with pacemaker, implantable cardioverter-defibrillator (ICD), and cardiac resynchronization therapy (CRT) device implantation rates per million inhabitants in 2016 in 56 European Society of Cardiology member countries being 592, 107, and 93, respectively.[1] The total number of CIED implantations in the United States surged by 96% from 1993 to 2008.[2] Transvenous access is recommended over the epicardial route for lead implantation, and a European Heart Rhythm Association survey from 2013 revealed that central venous access for lead insertion is typically established via cephalic vein cutdown (CVC) and subclavian vein puncture (SP).[3] Complications related to the procedure are not uncommon, and pneumothorax and lead failure are more frequent in SP compared to CVC, although bleeding events are comparable.[4] Axillary vein puncture (AP) has emerged as a new method with acceptable safety and success in the recent years.[5-7]

Although real-time ultrasound-guided central venous catheterization is widely used, it is not yet routinely used in the context of CIED implantation, to either check venous patency or guide the venous puncture, despite clear recommendations in expert consensus documents on the use of pre-procedural ultrasonography before opening the generator pocket.[8] Assessing the venous patency is particularly critical in patients with previous thoracic surgery, radiotherapy, or dwelling dialysis catheters or other device leads, so that multiple venipuncture attempts and lead/catheter damage can be avoided. Patients on antiplatelet or anticoagulant medicines would also benefit from fewer venipuncture attempts because it would lower their chance of vascular injury and pocket hematomas. In addition, other complications related to interruption of anticoagulation or bridging with parenteral anticoagulants, such as thromboembolic events and pocket hematomas, would be avoided. Surface ultrasound imaging for guiding venous entry has several advantages over fluoroscopy and venography, including reducing radiation exposure to patients and medical personnel as well as patient exposure to contrast agents.[9] This is advantageous, especially for iodine-allergic patients or those at risk of contrast nephropathy. Favorable outcomes regarding safety and procedural success were observed with ultrasound-guided AP compared with both SP[10] and CVC[11] in recent randomized clinical trials.

In this issue of *JACC: Case Reports*, Khan et al[12] have described the use of real-time ultrasound for guiding the entire single-chamber pacemaker implantation procedure. The authors highlight that they chose to employ cardiac ultrasonography in the reported case to prevent pneumothorax and cardiac perforation because the patient had frailty due to advanced age and a medical history of prostate cancer. Moreover, their approach included guiding lead positioning besides transvenous access, obviating the

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need for fluoroscopy throughout the entire procedure. The method that Khan et al have described allows for going completely fluoroless, which may be extremely beneficial in particular for the staff at the operating room. CIED implantation takes a lot of time—in a recent survey of CRT, the mean procedure time was 90 minutes and the mean fluoroscopy time was 13 minutes[13]—and the operator wears radiation-protective leaded aprons and other equipment even when venous access is ultrasound guided. The likelihood of occupational health risks, such as musculoskeletal injuries caused primarily by the cumulative impact of heavy personal protective lead aprons on the lumbar and cervical spine and lower limb joints, as well as the stochastic risk for cancer induction and cataracts due to radiation exposure, may be reduced as a result.[14,15] Avoiding radiation would help mitigate concerns related to reproductive health in both patients and physicians.

Transthoracic echocardiography (TTE) is a more accessible and affordable alternative to 3-dimensional mapping devices or intracardiac echocardiography that also may be used to guide the procedure. The use of agitated saline solution as noniodinated contrast media is an advantage to better delineate the anatomy. The addition of 3-dimensional echocardiography may also enhance visibility and better define anatomic features. Moreover, patients who cannot be mobilized to the operating room may benefit from CIED implantation guidance that uses only readily available noninvasive echocardiography. Along with the identification of anatomic features and anatomic variations, another benefit of completely ultrasound-guided CIED implantation from a cardiac standpoint is the capacity to evaluate functional tricuspid regurgitation by means of Doppler imaging. This approach may also allow earlier detection of procedural complications, such as heart perforation, pericardial effusion, or tamponade. Certain patient populations, such as obese patients, may have lower-quality ultrasonographic images, especially from the subcostal view, making visualization more difficult. In addition, in subjects with congenital anomalies of the major vessels, the procedure may take longer with this method.

Additional work is undoubtedly required to fully comprehend the efficacy and safety of this newly proposed approach, ideally in the context of a randomized clinical study. Single-chamber pacemaker implantation is generally straightforward, and it appears that right ventricular lead slack can adequately be assessed with the use of TTE. If fluoroless implantation is extended to dual-chamber devices, the right atrial lead can normally be seen reasonably well on TTE in the subcostal view and, again, it is possible to make a judgement about lead slack. A case series using TTE to guide dual-chamber CIED implantation did place a right atrial and right ventricular lead without fluoroscopy except for fluoroscopy at the end of the procedure to check lead position.[16] It would seem likely that fluoroscopy to assess final lead position and slack would be desirable in most patients, given that if repositioning is needed after the patient has left the implantation room that could increase the risk of infection.

A full evaluation of this technique should cover the need for rescue fluoroscopy and early complication rates. Research is required to see whether this may be used routinely for the implantation of dual-chamber CIEDs or even CRT devices. There is likely to be a significant learning curve, which would need to be a subject for study. Other methodologic questions that need to be further explained include whether using subcostal imaging in conjunction with other echocardiographic views would make it easier to see where the right ventricular septal pacing lead should be placed and whether this strategy would work for conduction system pacing.

In recent years, noninvasive multimodality cardiac imaging has been used more frequently in the electrophysiology laboratory. Until entirely ultrasonography-guided pacemaker implantation can be used in clinical practice, clinical studies should be undertaken to compare procedural success and safety and follow-up outcomes in patients randomized to a completely fluoroless procedure, and the use of complementary ultrasound guidance. Specific populations where this approach might be desirable need to be identified, such as pregnant women, who will probably benefit from zero-fluoroscopy pacemaker implantation. However, routine use is likely to be “a bridge too far” at this point in time given the familiarity of implanters with standard techniques and until there is stronger evidence indicating good outcomes and satisfactory complication rates.

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