Cephalic access with multiple leads may increase the risk of early ICD lead failure. Time to question the dogma?

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Despite extreme and undeniable progress in the concept of implantable cardioverter defibrillator (ICD) therapy over the last 40 years, the endocardial lead is still the weakest link of the system. Many efforts have been taken to improve the construction and consequently the durability of the lead. Not all of them were successful and some of the lead models proved to be technically imperfect, resulting in formal recalls. Similarly, patient- and procedure-related factors may strongly affect the lead reliability. The implantation of cardiac electronic devices (CIED) is considered to be a quite common vascular intervention. Also, there are strongly established opinions of best procedural manners, including the most optimal methods of vascular access during the CIED implantations.

In this issue of the Journal of Cardiovascular Electrophysiology, Barbhaiya et al. present an interesting retrospective analysis of 660 patients who underwent the ICD implantations in one center from 2011-2017. The goal of the study was to determine the risk factors for premature lead failure. Four implanted leads models were assessed: Biotronik Linox, Sprint Quattro, Durata and Endotak.

The main findings include:

The ICD lead implantation via cephalic access in multi-lead ICD systems may be a risk factor for premature ICD lead failure ($p<0.001$).

The overall risk of premature ICD lead failure was similar for all the analyzed lead models.

Concerns regarding the durability of Biotronik Linox were discussed and the study showed its equal reliability compared to the other leads.

Neither age nor gender were the risk factors for premature lead failure.

An optimal vascular access for the endocardial lead implantation was investigated in many studies.[1-4] So far, cephalic vein cutdown (CVC) was considered to be the method of choice, with the lowest rate of possible complications.[2,4,5] Meta-analysis performed by Benz et al. (30 000 patients, more than 50 000 leads) compared CVC and subclavian puncture (SP) and demonstrated lower risk of lead failure when CVC was adopted.[2] Axillary vein puncture (AP), especially when ultrasonography-guided, is a feasible technique and significantly reduces the probability of subclavian crush syndrome.[6-8] Unfortunately this method is not used by many operators. EHRA survey from 2013 showed that in more than 80% of participating centers, the preferred method for venous access was either CVC or SP.[9] What is worth emphasizing, in the study of Barbhaiya et al., axillary access was most often used for lead insertion – 76.8% (61-88%, dependently on the lead model). This fact may potentially explain the main study finding. It is also consistent with the interesting results of the PAIDLESS study presented in the paper of Shaikh et al.[3] They showed that experienced operators preferably choose subclavian and/or axillary access (62% of implants), whereas low-volume implanters generally use cephalic vein approach (63%). High-volume operators are also less likely to

experience lead failure.

An important issue to discuss is the number of leads inserted via cephalic vein. The routine practice, also applied by Barbhaiya and colleagues, includes the placing of atrial and right ventricular leads via cephalic access, if possible. Inserting one or two leads is usually not a problem. There are many inventive ways for doing this, described in literature. Some operators go even further – they use cephalic vein to implant all three leads of cardiac resynchronization therapy (CRT) systems with the success rate of 87.7% - 91.7%.[10,11]The question of long-term reliability of the leads implanted in such a way is still open. They are tightly packed in one small vessel and possible lead - lead interaction may contribute to their failure. Especially the ICD leads, by definition more complex and sensitive, are prone to damage in these circumstances.

Another possible *locus minoris resistentiae* is the site of cephalic vein ligation after the lead insertion. The line between an adequate and too strong suture tightening is quite narrow. The effort to stop the bleeding from the vein may cause ligation-induced lead insulation damage. Recently, Kajiyama et al. proposed a novel technique for the ligation of the cephalic vein during a two-in-one insertion of the leads.[12] It reduces hemorrhaging without decreasing the lead safety.

The discussion about the benefits of different vascular access should include the potential disadvantages of future lead extraction, especially in the multi-lead systems. Inserting more than one lead via cephalic vein may determine more problematic transvenous lead extraction procedure (TLE). It may also necessitate the extraction of the functioning lead because of its periprocedural damage during the TLE of the initially targeted lead.

The reliability of ICD leads is certainly the most important feature. During the last decades several lead models produced by different manufacturers were recalled because of their serious technical defects. Numerous concerns and divergent literature data regarding the durability of the Linox lead were the premise for the authors to conduct the discussed study. An important observation is that all analyzed lead models, including Linox, were similar in terms of performance (p=0.769).

Young and physically active patients were traditionally believed to have a higher risk of lead damage because of the intensive mechanical interaction between the lead and anatomical structures of costoclavicular space. This observation was not confirmed by the authors of the commented paper.

The study has several limitations and they are all listed by the authors. The lack of multivariate risk factors analysis is the most important drawback. It could not be performed due to the low overall event rate. All interesting study findings require validation and further investigation.

As the ICD lead failure is still a serious problem, the study investigating possible risk factors is always of great importance. With all the limitations, the paper presented by Barbhaiya et al. may be an important guide in dealing with the vascular access during CIED implantations. It sheds new light on the dogma of superiority of cephalic access. What is particularly important in the study outcome and what I personally find a very strong recommendation – is the conclusion that the multiple lead systems should be avoided, if not indicated, especially when combined with cephalic venous access. One possible solution is to use cephalic vein for one lead only. Prospective randomized studies directly comparing axillary and cephalic access would be highly desirable in order to come closer to the idea of the best vascular approach for the endocardial lead implantation.

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