Looking for Lead Adhesions While Planning for Transvenous Lead Extraction

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Background

The first implantable pacemaker was placed in the 1958, ushering in a new frontier of cardiovascular medicine. Since that time, implantation of cardiovascular implantable electronic devices (CIED) has exploded. The growth in CIED implants has been accompanied by a similar growth in the need to remove them. With the development of specialized tools and advancement of our understanding of transvenous lead extraction

(TLE), success rates are excellent, typically reported around 98%. There are, however, challenges. Over time an ingrowth of fibrous tissue binds the leads of these devices to surrounding vascular and cardiac structures and to other leads. This tissue creates most of the challenges faced during transvenous lead extraction. The spectrum of ingrowth and adhesion of the leads is quite variable, and we have a long way to go in our understanding of how to predict these adhesions.

Multiple modalities have been shown to be effective in detecting adherence between the leads and other structures. CT, transesophageal echo (TLE), intravascular ultrasound (IVUS), and intracardiac echo (ICE) have all be studied. Patel et al detected some degree of adherence in 86% of subjects and severe adherence with the lead outside the contrast lumen in 19%[1] In another study evaluating CT in TLE, Svenberg et al reported severe lead adhesion in about 45% of subjects.[2] TEE has also been evaluated to detect adherence to the SVC and cardiac structures. Nowosielecka reported binding to the SVC and right heart structures in 34% of patients.[3] IVUS and ICE may also be used to assess lead binding to cardiac and venous structures. Using IVUS, Beaser et al reported high grade adherence in 25% of patients.[4]Sadek et al used ICE to look for lead binding to the SVC or myocardium and detected significant binding in 36% of patients.[5] While, the modalities differ in how they detect these adhesions and, to some degree, the structures being assessed, together, the studies tell us that adhesions binding leads to other structures is common.

Findings and Implications

In the current issue of JCE, Aboelhassan et al report their findings using an ipsilateral venogram to evaluate for venous stenosis and lead-venous adherence. They found that the results of this simple venogram could help predict the complexity of TLE. One hundred and five patients were enrolled in the study with a median of two leads requiring extraction in each and a median dwell time of 8 years. About half of the patients were undergoing TLE for infectious indications and a little over half had implantable cardiac defibrillators (ICDs). A dedicated preoperative ipsilateral venogram was performed in all patients assessed for the degree of venous stenosis and lead-venous adherence. TLE was performed in a stepwise fashion in all patients, progressing from simple traction to non-powered sheaths to powered sheaths (laser and mechanical) and finally, to snares via femoral access.[6]

Lead-venous wall adherence was defined as extensive if measured contact or surrounding haziness was [?] 50mm or if there was more than 10mm distance between any lead and the venous lumen. Venous stenosis was also assessed and was classified as not significant (<50%), moderate (51-70%), severe (71-99%) and occlusive (100%). While total number of leads was the only characteristic associated with occlusion, Total number of leads and age of the oldest lead were both associated with lead-venous adhesion.[6] The study may underestimate the prevalence of lead-vein adherence and venous stenosis. Venograms were performed in a single projection, which may fail to detect some areas of stenosis or adherence which might have been discovered in another projection or by a three-dimensional study. Nevertheless, this simple test detected severe stenosis or occlusion in 20% of subjects and lead adherence in almost half.

Of course, detection of adherence by venogram or other imaging techniques is only useful if it helps guide decision-making for the planned procedure. Aboelhassan et al found that detection of lead-venous adherence may, indeed, guide preparation for TLE. The authors report that lead-vein adherence was associated with higher TLE procedural complexity. Patients with extensive lead-venous adherence required advanced tools in 72% of cases and fluoroscopy time was 14.0 min compared to 34.5% need for advanced tools ($P<0.001$) and mean fluoroscopy time of 5.1 min ($P<0.001$) in those without extensive adherence.[6] This association between lead-venous adhesion and increased complexity of TLE mirrors what has been described for other imaging modalities.

Patel et al reported that when leads are seen outside the vein contour by preoperative CT scans, procedure times are about one-third higher and fluoroscopy times about 80% higher.[1] Lead adherence to central venous structures by CT is also associated with the need for larger sheaths and more than a doubling of laser times.[7] Similarly, the finding of binding of leads to other leads or to the right atrium or right ventricle by TEE is associated with about a doubling of the likelihood of technical difficulties during TLE.[3] Other studies utilizing

IVUS and ICE have also reported an association between lead adherence and increased TLE complexity.[4,5] Interestingly, Beaser et al. reported that the finding of minimal adhesions by intravascular ultrasound were associated with lower complexity during TLE even in the setting of other clinical factors which typically predict higher complexity such as lead dwell time, presence of multiple leads and the presence of an SVC coil.[4] In fact, even adhesions in the pocket have been associated with increased TLE complexity and the need for a higher number of extraction tools.[8]

While Aboelhassan et al. found an association between lead-venous adherence and procedure complexity, there was no such association in patients with venous occlusion. It would seem to follow that venous occlusion would imply greater fibrous ingrowth and binding to the leads which, in turn, would impact the difficulty of TLE. While it is tempting to think of lead-vein adherence and venous occlusion in the same light, the current study demonstrates they can impact TLE quite differently. The authors a found similar need for advanced tools (53.3% vs 52.2%, $P > 0.9$) and fluoroscopy times (10.7 min vs 8.0 min, $P = 0.6$) in those with and without venous occlusion. Furthermore, they report complete procedural success in 100% of subjects with total occlusion and 97.8% in those without ($P > 0.9$).[6]There are conflicting data on this point. Li et al studied patients with a venogram and reported that among those with occlusion, procedure times were more than 25% higher and fluoroscopy times were more than 50% higher compared to those without occlusion.[9]Czajkowski et al also reported an association between the finding of occlusion on venogram and longer procedures and need for more advanced tools.[10] Conversely, other studies utilizing either CT or venography found no difference in TLE complexity between patients with and without occlusion.[7,11]

While the finding of lead-venous adherence predicted complexity of the extraction procedure, no difference was found in complete success rates of extraction between those with and without adherence. There are likely several reasons for this finding. In general, the success rates for TLE are very high. The complete success rates from most large studies fall in the range of 95-97%.[12,13] In this study, reflecting the results of most major trials, the complete procedural success rate was excellent with reported rates of 98.0% in patients with extensive adherence and 98.2% in those without ($P > 0.9$).[6] So, even in difficult cases, complete success was common. Furthermore, the authors report the results from a single center which serves as a national referral center for TLE. Multiple studies, including a relatively recent report from the ELECTRa registry, have reported worse outcomes in low volume centers including lower success rates and higher risk of procedure-related death.[14,15] So, while lead adherence was not associated with significantly higher failure rates in this study, we should not assume that excellent outcomes are a given in all centers regardless of complexity.

The authors of the current study are careful to report that while lead-venous adherence increased TLE complexity, the finding was not associated with a statistically significant increase in risk of the procedure. Here, the size of the study likely limits the ability to detect differences in risk. While complications of TLE may be catastrophic, the event rate is quite low. Most larger studies of TLE report major complication rates of around 1-2% and minor complications of about 1-6%.[12,13,16] Intuitively, one might expect higher rates of vascular lacerations in patients with venous adherence, but, like other major complications, those rates are very low and thus differences will be difficult to detect in smaller studies.

While statistical significance was not achieved in this study by Aboelhassan et al, complications were more than doubled in the group with lead-venous adhesion compared to those without (18% vs 7.3%). It is tempting to look at these findings and assume they would reach statistical significance in a larger trial, but adherence of the leads to the veins and other structures is just one piece of the puzzle. The risk of major complications is influenced by a myriad of patient, device and procedural factors. For instance, female gender has been identified as a risk factor in several studies.[17-19] Markers of patient frailty such as a depressed LVEF, thrombocytopenia, elevated INR and low BMI are also associated with increased risk of complications in TLE.[12,20] Other patient factors such as age at initial implantation and number of prior device procedures can impact risk.[18] Device factors including number of leads, type of leads and the presence of abandoned leads may play a role.[18,21-24] Finally, center and operator experience may influence the risk of TLE.[15,25]

While the difference in complications in patient with lead-venous adherence in this study did not reach statistical significance, other studies support an association. In the study by Aboelhassan et all, lead dwell time and number of leads were both positively associated with a higher likelihood of lead-venous adherence, a finding supported by other studies as well.[6,13] These predictors of adherence are positively associated an in the increase the risk of TLE. The Canadian Lead Extraction Risk (CLEAR) study identified advanced lead age and extraction of 2 or more leads, among other factors, as contributors to increased risk of major complications during TLE.[17]Derived from the ELECTRa Registry, the EROS score helps identify patients at risk for major complications during TLE. The highest score, EROS 3, is assigned if subjects have a pacemaker lead >15 years from implant or an ICD lead >10 years from implant. Patients with this score are more than three times more likely to suffer major complications including death during TLE.[25]While we should not expect smaller studies to identify associations with major complications in TLE, it is reasonable to believe that factors that increase the complexity of TLE may impact risk.

Conclusion

As with any procedure, the preparatory phase of TLE is critical, allowing the physician to anticipate challenges, ensure the availability of necessary tools and personnel, and ultimately, to counsel the patient on the safety and likely outcomes. The study by Aboelhassan et al in this issue of JCE supports the value of a simple venogram in planning for TLE. Ultimately, though, more work must be done to fully define the role of venography in this regard. A venogram cannot supplant CT, TEE, IVUS or ICE and in some cases, the added value may be minimal. Those other imaging modalities provide a depth of information that venography does not. CT, for instance, should be able to detect some adherence which might be missed by venography in a single projection. Additionally, CT provides a better assessment of lead adherence to cardiac structures. TEE, ICE and IVUS can all detect adherence of the leads to the veins as well as other structures and provide feedback in real time. In fact, TEE been shown to help rapidly detect major complications and provide reassurance during periods of transient hypotension.[9]

Aboelhassan et al should be commended for their excellent work demonstrating the ability of a simple venogram to predict complexity of TLE. Ipsilateral venography may deserve greater consideration as part of the planning for lead extraction. Still much remains to be done to improve our planning and thereby improve both safety and outcomes of TLE.

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