Rationale For and Use of Lumenless Pacing Leads

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Abstract

Introduction Most currently available pacing and defibrillation leads utilize a stylet-based design that facilitates implantation. This has advantages, but also increases the lead diameter and adds the potential for metal fatigued-based conductor failure. Methods A systematic literature search was conducted, and the authors add their twenty-year experience with this lead design. Results The global experience with lumenless leads was reviewed both for "standard" positioning and with conduction system pacing. Methods for both placement and system modification are reviewed. Conclusions Lumenless leads have the potential to improve the durability of endocardial pacing and facilitate conduction system pacing.

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Introduction

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Methods

A systematic literature search was conducted, and the authors add their twenty-year experience with this lead design.

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Conclusions

Lumenless leads have the potential to improve the durability of endocardial pacing and facilitate conduction system pacing.

Rationale for lumenless leads

Lumenless leads were first developed over 20 years ago with an aim to reduce the diameter of pacing leads and allow precise catheter delivery while improving reliability[1]. Smaller diameter leads reduce subclavian crush, venous and valvular stenosis, and improve the ease of extraction[1-3] . Currently, the model 3830 lead (Medtronic, Inc., Minneapolis, MN) is the only available lumenless pacing lead. This lead has demonstrated excellent acute and long- term electrical performance[4, 5]. Figure one depicts the difference between the design of this lead and others. This lead utilizes a flexible inner cable as the core conductor coupled to a fixed, electrically active helix. The flexible central cable is intended to reduce the risk of fracture, while also providing a stable platform for lead extraction. There is now a similarly designed defibrillation lead in clinical trial[6].

These leads were initially used for standard endocardial pacing but are now commonly used for selective conduction system pacing. The steerability of the delivery system allows for ease of site selection, while the small diameter of the lead allows for ease of tissue penetration. Interest in directly pacing the conduction system began in 1978[7]. Modern conduction system pacing first targeted the bundle of His and now more commonly targets the matrix of the left bundle by attempting to penetrate into the interventricular septum[8, 9].

Construction of the lumenless lead

The currently available 3830 pacing lead and the investigational Medtronic Next Generation Defibrillation Lead have a unique design. By eliminating the central lumen, which contributes about 40% of the diameter of a standard 7 French pacemaker lead, the 3830 lead is only 4.1 French diameter[10]. Traditional coaxial leads employ a coiled inner conductor with a central lumen, allowing for the insertion of shapeable stylets to facilitate steering and placement. This inner coiled conductor and lumen has two adverse effects: first it requires space necessitating a larger lead diameter and second the central lumen creates susceptibility to kinking with flexion when under tight bending conditions. This kinking can lead to a point of repetitive localized stress causing metal fatigue, potentially resulting in conductor fracture. The two lumenless leads described contain a flexible, high tensile strength cable as the inner conductor which is intended to avoid this issue by reducing stress in high bending conditions. One difference with lumenless leads is the method of extraction when needed. During extraction, locking stylets are typically placed into the inner lumen of coaxial leads that expand to grip the inner coil surface to allow for traction on a high tensile strength structure. This is not possible with lumenless leads. Rather, the central cable may be used itself for traction. This cable does not stretch during traction compared to a coiled conductor and allows for traction directly to the lead tip appropriate for small diameter lead use conditions. In addition, since the lead helix is not retractable, it is designed to straighten with about 2 Kg of force reducing the potential of myocardial avulsion[11].

Implantation tools and techniques

While many of the fundamental aspects of device implantation are no different when utilizing a lumenless lead, the process of placing the lead in the desired location within the heart is fundamentally different. When using a standard stylet-driven lead the stylet can be withdrawn and shaped to allow the implanter to direct the lead. The stylet is a stainless-steel wire (26-29 gauge) designed to direct the lead tip by torquing the stylet wire within the lead inner lumen with the stylet knob at the proximal end. The shape applied to the stylet is critical to achieve the desired location. When implanting a lumenless lead the implanter utilizes either pre-shaped or deflectable delivery catheters to direct the lead. The intent of utilizing catheter delivery is to provide increased control over positioning the lead tip in the desired anatomical location. [10]. For right ventricular lead placement, we target placement on the interventricular septum and mainly utilize either a curved catheter with a short 90-degree secondary curve (C315 His), a straight deflectable catheter with a short 90-degree secondary curve (C304-HIS), or for large ventricles a straight deflectable (C304-L69 and C304-S59) catheter. For atrial lead placement we utilize either a J-shape catheter (C315J) or the straight deflectable catheters mentioned above which can allow for placement on the interatrial septum. These designs are intended to create the flexibility for lead placement anywhere in the right atrium or ventricle. The non-deflectable sheaths have an outer diameter allowing for introduction through a 7F outer sheath while deflectable sheaths have an 8.4F outer diameter and must be placed through a 9 F outer sheath. While the delivery catheters can be placed directly into the vasculature, the potential advantage of using an outer sheath is that it avoids the need to regain vascular access should a lead become dislodged during or after removal of the delivery catheter. While we recommend the routine use of separate venipunctures, if an outer sheath is used, a second guidewire can be placed into the outer sheath alongside the lead allowing for retention of vascular access. For these reasons, we suggest the use of an outer sheath when beginning to use the 3830 lead.

Endocardial vs. Subendocardial Electrode Placement

The most important consideration in determining how to implant a lumenless lead is to determine the target of the electrode. With standard lead implantation in the atrium, on the ventricular myocardium or even on the His bundle, the desired outcome is implantation of the electrode at the level of the endocardium. In the case of "deep septal pacing" the goal is to penetrate the lead well into the myocardium, capturing the left bundle. The technique of fixation is dramatically different between the two. For endocardial placement, it is important to limit the number of turns of the hub of the lead to no more than 4 or 5 turns. For deep septal pacing multiple turns are used in order to embed the lead into the myocardium. The use of this technique at the right ventricular apex or in the atrium could significantly increase the risk of perforation.

Endocardial/Shallow Lead Fixation

For endocardial fixation of lumenless leads the delivery catheter is directed to the desired chamber with the tip pointing toward the targeted tissue. The lead is then advanced through the catheter and out to make contact with the tissue, once contact is established the lead is rotated clockwise to secure the fixation helix. The Medtronic 3830 lead has a significantly smaller diameter and tip surface area than most leads, which means that for a given amount of forward force applied the tissue, pressure exerted is higher. With this in mind caution should be taken to not extend the lead out of the delivery catheter if it is firmly pressed against tissue, rather the delivery catheter should be back from the endocardial surface within the targeted chamber and the lead, with its flexible body, advanced to the tissue. The considerable flexibility of the lead prevents significant forward force from being applied to the tissue and reduces the risk of cardiac perforation. When endocardial fixation is desired such as in the right atrial appendage, 4 to 5 clockwise rotations are sufficient to achieve tissue anchoring[10]. Over-torquing the lead may well result in penetration into and through the endocardium. The lead should be rotated with careful attention to the header of the lead, observing the labels to count the rotations, as the number of rotations cannot be assessed fluoroscopically. Fixation can be assessed by introducing and withdrawing lead slack while observing the stability of the lead tip under fluoroscopy. Implantation related injury current should also be present on the bipolar electrogram, See figure 2. If injury current is not observed after initial placement, we suggest applying 1-2 more clockwise rotations

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to the lead and reassessing; if there is still no injury observed we will typically move the lead to a different position. Once fixation is confirmed the delivery catheter is slit and the lead can be anchored to the fascia.

When placing the lead in the right atrial appendage, endocardial or shallow fixation is desired. Here we typically utilize the pre-formed J shaped delivery catheter (C315J), which is directed to the mid right atrium. We then apply clockwise torque to direct the curvature anteriorly. The lead is advanced from the catheter superiorly to the right atrial appendage when tissue contact is observed (either the lead flexes slightly or the delivery catheter is pushed posteriorly). The lead should not be advanced any further and should be affixed with 3-4 clockwise rotations. If the lead achieves tissue contact before the body of the lead is out of the catheter, then the delivery catheter is likely too high in the atrium directly opposed to tissue and should be advanced. We do not recommend placemen of this lead on the atrial free wall.

His Bundle Pacing

When targeting the bundle of His either the C315His or the deflectable C304-HIS delivery catheters are typically used. The S10 and C304-L69 can also be used. There are two general methods for locating the His, sense mapping and pace mapping. With either technique the lead is advanced nearly to the end of delivery catheter without exposing the fixation helix. When sense mapping, bipolar recordings from the lead are used to locate the His deflection. Alternatively, if femoral access is in place a standard multipolar catheter can be used to identify the location of the His bundle. In our experience, pace mapping allows for more efficient identification of the His bundle location. With this technique the catheter is directed to the septal right ventricle just beyond the tricuspid annulus and unipolar pacing from the lead tip at moderate output (5V for 0.5ms) is performed. The catheter can then be manipulated back to the tricuspid annulus until selective His capture (short stim to QRS interval with QRS complex identical to conducted QRS, Figure 3) is observed. The lead helix is then advanced just out of the catheter and with 4-5 turns, affixed at this site. Obviously, a combination of these techniques can be used as well.

Left Bundle Branch Area Pacing

When targeting the left bundle branch directly we typically utilize the deflectable C304-HIS catheter, though the C315 His catheter can also be used as well as the C304-L69. Several methods of achieving left bundle capture have been described, typically we utilize an anatomic approach and target a site approximately 2cm apical to the tricuspid annulus and slightly inferior to the level of the His. When targeting the left bundle branch the lead tip must be advanced into the interventricular septum, usually to the depth of the ring electrode[12]. In this instance the principles described above to avoid cardiac perforation must be modified as tissue penetration is desired. The delivery catheter must be forcefully opposed to the interventricular septum with a moderate amount of forward pressure. When the catheter tip is directed to the desired anatomic location as identified in the right anterior oblique (RAO) view, the lead should then be advanced into the interventricular septum in the left anterior oblique (LAO) view to allow for assessment of depth of tissue penetration. Clockwise rotation should be applied to the lead while applying very gentle forward pressure. Almost invariably more than 5 rotations will be needed to achieve sufficient tissue depth for left bundle capture. After initial placement unipolar signals can be examined for a left bundle potential (not always observed even at sites of excellent pacing) then pacing is performed from the lead tip and the QRS morphology is evaluated. Unipolar pacing impedance should be high (> 800 ohms) when the lead tip is within the septum. The depth of penetration can also be assessed by unipolar pacing the ring electrode to assess whether the ring is buried. If left bundle capture is not observed further clockwise rotation should be applied, in many instances >10-15 rotations will usually be necessary. In some cases, delivering 4-5 rapid clockwise turns will improve tissue penetration as compared to a slower cadence of rotation. There have been multiple descriptions of how to assess left bundle capture[8, 13]. If the unipolar pacing impedance ever begins to decrease after the lead advances into the septum the lead should not be advanced any further, as this may be a sign the fixation helix has reached the left ventricular endocardial surface. In some instances, it will be challenging to advance the lead into the septum due to lack of support from the delivery catheter. In these cases we recommend ensuring that the delivery catheter is truly abutting the tissue; after initial lead fixation and while applying gentle backward traction on the lead the catheter can be advanced for more

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support. If it remains ambiguous whether the catheter is against the septum, contrast injection through the catheter side port can be instructive, in our experience this is rarely necessary. Finally, if multiple attempts have failed to achieve left bundle capture our experience suggests that attempting placement at a slightly more apical and inferior position will often be successful, likely due to the larger and more arborized left posterior fascicle (Figures 4,5).

Modification of lumenless leads

The lack of a central lumen in the 3830 pacing lead changes the available techniques for modifying a pacing system. In a standard Bisping (extendable-retractable) active-fixation lead, if the lead were to dislodge or develop a high threshold, it could simply be unscrewed and then affixed to a new location. This is not the case with these lumenless leads. The lead must be replaced. In addition, chronic model 3830 leads should not be re-used. This lead has steroid that is externally applied to the electrode. The product manual specifies that there is a target amount of 17.2 mcg of beclomethasone dipropionate [10], which elutes over a period of time. After several weeks, one would expect there to be much less steroid on the lead. Therefore, while acute repositioning is certainly possible, chronic repositioning, is not recommended because the benefits of a steroid-eluting lead may not be present. In contrast, the investigational Next Generation Defibrillator Lead utilizes a standard collar that allows steroid elution over a longer period of time.

Extraction of lumenless leads:

Extraction of chronically implanted lumenless leads poses other challenges but are mitigated due to a smaller surface area compared to standard leads. Several series have described extraction of these leads[14, 15] . There are several differences in the design that impact extraction. First, the fixation helix is designed to straighten with modest force[11] . The rationale for the design of the fixation helix that straightens out is that torque transmission to the tip may vary depending on lead dwell time and patient response, potentially not allowing to unscrew these leads. Attempts to unscrew chronically implanted lumenless leads are likely to complicate extraction attempts as the lead tip stays in place and torque may lead to bending or intravascular loops.

Second, the central cable has considerable tensile strength, and it does not elongate with traction as compared to traditional leads prepared with locking stylets that can slip with high traction force. However, caution needs to be taken when applying traction not to exceed the tensile capability of the inner cable. If the conductor cable detaches from the lead tip, the lumenless lead loses its tensile strength and the coiled outer conductor will unravel[11]. This can make complete system extraction difficult and require the use of femoral tools to complete the extraction. Fortunately, in our experience, extraction tools are generally not needed for removal of these leads unless they have developed calcification. If calcification is present, or the lead cannot be removed with gentle traction, the use of small diameter cutting tools(laser or mechanical) is needed. Therefore, proper lead preparation ensuring adequate engagement of the inner cable is required to provide appropriate rail strength for extraction. If extraction tools should be used, we cut the lead and expose the inner cable. After folding the cable onto itself, a lead extender such as a Bulldog® device (Cook Medical, Bloomington, IN) can be applied. Alternatively, the lead can be left intact and the silicone around the pin and ring can be shaved off to allow an up-sized cutting sheath to pass over the intact lead. However, this requires quite a miss-match between the 4.1 French lead diameter and a 14 French extraction sheath. We feel that the lowest risk approach is to use a smaller sheath and the traction device.

Clever techniques have been used with standard leads to maintain venous access at the time of lead removal when the lead requiring modification remains mobile, such as placing a wire under the outer insulation and advancing the lead and wire into the vasculature[16]. This technique will not work with the lumenless leads due to lack of a stylet to allow for lead advancement. A method that has been successful for us is to free the lumenless lead from the endocardium but letting it remain in the heart. A snare is then advanced from the femoral vein and the lead is grasped firmly. The lead (with the snare attached) is then removed from the access site, externalizing the snare delivery catheter. The lead can then be released, and the snare removed from its catheter, which is now left entering the femoral vein and exiting the CIED venous entry site. A

stiff guidewire is then advanced through the catheter, which is then removed, and the operator is left with a guidewire in place for placement of a new lead. Due to the possibility of venous stenosis along the course of prior leads we typically use a stiff guidewire for this technique such as the Supra Core® wire (Abbott Medical, Chicago, IL).

Future Directions

A clinical trial has now begun on a defibrillator version of this lead (ClinicalTrials.gov Identifier: NCT04863664). In this trial the lead will be used in a standard endocardial position in the right ventricle. This next generation defibrillator lead is 4.7 French in diameter and utilizes a single right ventricular ICD coil as the outer conductor. Sensing is thus obligatorily from tip to coil. Standard measures of efficacy will be measured including the defibrillation threshold and lead diagnostics. This trial also uses an interesting approach of coupling "virtual patients" that represent data from rigorous engineering bench evaluation that has been demonstrated to be able to predict lead conductor failure

Conclusions

Lumenless leads have been available for many years and can be used for traditional pacing applications as well as selective conduction system pacing. Growth in conduction system pacing has led to increased utilization of lumenless leads in recent years[17] . Potential advantages of the lumenless lead include its small diameter, ease of site-specific placement, and ease of extraction.

Figure 1. Design of cardiac implantable electronic device leads. (a) typical coaxial pacemaker lead (b) lumenless lead. The lumenless lead has a flexible cable and an inner conductor surrounded by insulators and a coiled outer conductor. The standard coaxial lead has a lumen, contains no cable and is larger in diameter.

Figure 2. Implantation related injury current. Panel (a) displays essentially no injury current and panel while (b) displays desirable injury current.

Figure 3. His Bundle Pacing. Example of His bundle pacing, not pacing artifact with isoelectric interval followed by narrow QRS identical to sinus rhythm.

Figure 4. Left Bundle Branch Pacing. Example of pacing the left sided conduction system, in this case the proximal left posterior fascicle. This is evidenced by relatively narrow QRS, short LVAT, r' in V1, and left axis deviation.

Figure 5. CT Scan of 3830 lead position achieving left bundle capture. Position of LB pacing lead. Axial CT scan image showing pacing lead at mid septal position with tip approximating the LV endocardium resulting in left bundle branch capture.

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Native Rhythm   Pacing Left Posterior Fascicle