Novel Method for Placement of Right Ventricular Pacing Lead - Initial Experience with the Right Ventricular Introducer Sheath

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Summary

Current methods for advancing pacing leads to the right ventricle (RV) apex require lead manipulation using multiple stylets. Difficulty traversing the tricuspid valve may prolong the procedure with clinical and economic consequences. A new technique for placing RV leads using a RV Sheath was evaluated for efficacy and safety. After left subclavian venous access was obtained, a 135 cm J-tipped 0.035 inch guidewire was advanced to the right atrium. A 45 cm long RV Sheath was advanced over the wire to the superior vena cava. Wire and dilator were removed and a balloon flotation catheter was advanced. The balloon was inflated upon exit from the RV Sheath. Under fluoroscopy, the flotation catheter was advanced to the RV outflow tract. The Sheath was advanced over the flotation catheter until its tip reached the RV apex. The balloon was deflated and the flotation catheter removed. The pacing lead (Synox SX60BP, Biotronik) was passed through the Sheath until the lead tip reached the RV apex. The Sheath was peeled away leaving the lead in place with its tip in the RV apex. This study demonstrates that a ventricular pacing lead can be safely advanced to the RV apex without manipulation using the RV Sheath advanced over a balloon-flotation catheter. Excellent acute pacing and sensing thresholds indicate attainment of optimal lead position in the RV apex. Procedural success and rapidity may be improved by using a "slit-away" rather than "peel-away" sheath design and by using a sheath with an inner lubricious coating and variable flexibility with an atraumatic distal segment but firmer, kink-resistant proximal and mid segments.

Key Words

Ventricular pacing lead, placement of pacing leads

Introduction

Regardless of whether a dual chamber or single chamber pacing device is implanted, the overwhelming majority of patients in whom a permanent pacemaker is implanted receive a ventricular pacing lead. Safe methodology has evolved over time and has been well described [1]. The two techniques most frequently used in permanent pacemaker implantation typically obtain venous access by one of two methods.

The subclavian vein is punctured with a thin-walled, large-bore needle and a guidewire passed into the vein. The needle is removed and an introducer sheath is advanced over the wire into the sublclavian vein as originally described by Littleford [2]. The pacemaker lead is advanced into the venous circulation through the introducer sheath. Current introducer sheaths are of sufficient length only to provide access to the subclavian vein and, in some smaller patients, to the superior vena cava. Alternatively, a pacemaker lead can be introduced by surgically isolating the cephalic vein and introducing the lead under direct visualization via a venotomy [3].

Regardless of the technique used to obtain venous access, the pacemaker lead must then be advanced via the superior vena cava into the right atrium (RA) and then manipulated across the tricuspid valve (TV) into the right ventricle (RV) and then further advanced over right ventricular trabeculae to the RV apex to obtain optimal pacing position. Ventricular lead placement, particularly with tined leads, can sometimes be cumbersome and time consuming. Difficulties most frequently involve passing the lead across the tricuspid

valve due to interactions of the tines with the TV apparatus, inadvertent passage into the coronary sinus (CS), and difficulty passing the lead distally to the RV apex due to interaction of the tines with RV trabeculae. Pacemaker leads are soft and flexible and are not intrinsically "steerable" and thus require use of curved and straight stylets to transiently stiffen the lead and facilitate directional manipulation of the lead from the RA across the TV into the RV. To ensure that the lead has not been inadvertently advanced into the CS, many operators advance the lead into the RV outflow tract or pulmonary artery first before withdrawing the lead back into the RV.

Thus, problems with the standard method for ventricular lead placement are that the technique

1) requires extensive lead manipulation of an intrinsically flexible, non-steerable lead;
2) often requires multiple stylet exchanges as well as stylet shaping;
3) has potential for inappropriate lead positioning, (e.g. CS placement); and
4) is time-consuming, thus increasing the duration of surgery and exposing the physician, staff, and patient to excess fluoroscopic radiation.

The objective of the present study was to evaluate a method of ventricular lead placement that requires little or no lead manipulation, eliminates the need for multiple stylets, and decreases the risk of inappropriate lead placement in the coronary sinus while maintaining or increasing the safety and rapidity of the procedure. The RV Sheath achieves these objectives by

1) using a balloon-tipped, flow-directed catheter to quickly obtain RV access;
2) using a long introducer sheath which is passed to the RV apex over the balloon-tipped catheter; and
3) after removing the balloon-tipped catheter, advancing the ventricular pacing lead directly to the RV apex through the RV Sheath.

Materials and Methods

Twenty-eight patients undergoing dual chamber (DDD) or single chamber (VVI) pacemaker implantation were randomized to have the ventricular pacing lead placed using either the RV Sheath or a standard, short introducer sheath. In the 15 patients randomized to the RV Sheath group, the left subclavian vein was punctured using a thin-walled, large-bore needle and a 135 cm J-tipped guidewire was advanced under fluoroscopy to the superior vena cava (SVC). The 45 cm peel-away style RV Sheath was advanced over the guidewire until the tip of the dilator reached the RA. The guidewire and introducer sheath dilator were removed and a single lumen 7F balloon-flotation catheter was advanced through the introducer sheath. When the balloon flotation catheter was seen under fluoroscopy to exit the introducer sheath, the balloon was inflated. The introducer sheath was held fixed in position and the balloon flotation catheter was advanced to the RV outflow tract or pulmonary artery position. The balloon flotation catheter was then fixed in position and the introducer sheath was advanced until its tip was in or near the RV apex. The balloon was deflated and the flotation catheter removed keeping the RV Sheath fixed in place with its tip in or near the RV apex. The ventricular pacing lead was passed through the introducer sheath and advanced until the tip of the lead reached the end of the RV Sheath and approached the RV apex. The RV Sheath was then peeled away taking care of maintain the position of the pacing lead in the RV apex. Further positioning of the lead within the RV was performed if necessary.

In the 13 patients randomized to the standard sheath group, the left subclavian vein was punctured using a thin-walled, large-bore needle and a short, 135 cm J-tipped guidewire was advanced under fluoroscopy. A standard-length introducer sheath was advanced over the guidewire and the guidewire and dilator were removed. The ventricular pacing lead was advanced through the introducer sheath until the tip was in the SVC and the introducer sheath was then peeled away. The lead was manipulated using a combination of curved and straight stylets until the lead tip was across the TV and into the RV.

Total elapsed time and fluoroscopy time were recorded from the time of subclavian vein access until the time of the first pacing and sensing threshold, and from the time of access until the final lead position was obtained and the lead was sutured in place. Pacing and sensing thresholds and lead impedance values were recorded.

Results

The ventricular pacing lead was successfully placed in all patients. Lead placement using the RV Sheath was successful in 13 of 15 patients, or 87%. In the two patients in which the pacing lead could not be placed

	Time to Threshold	Fluoro Time ot Threshold	Time ot Lead Suture	Fluoro Time to Suture
RV Sheath (n=15)	204 ± 61	81 ± 36	500 ± 249	227 ± 177
Standard (n=13)	209 ± 99	81 ± 78	480 ± 223	170 ± 109

Table 1. Elapsed time and fluoroscopy time for both groups (all times in seconds, P = NS for all comparisons).

using the RV Sheath, the lead was successfully positioned using standard techniques employing curved and straight stylets. There were no intra-operative complications although one patient in the RV Sheath group later developed a respiratory arrest and expired. Chest x-ray confirmed appropriate pacing lead positions and excluded pneumothorax, and echocardiography excluded hemopericardium due to ventricular perforation or other cause. There was no evidence that the events leading to the patient's demise were related to her pacemaker procedure.

The total elapsed time and fluoroscopy time for each group are displayed in Table 1. The mean time from venous access until first pacing threshold was 204 ± 61 seconds for all RV Sheath patients (n = 15) compared to 209 ± 99 seconds in the standard sheath group (P = NS). Mean time from venous access until first pacing threshold for successful RV Sheath patients (n = 13) was 194 ± 58 seconds (P = NS). Mean fluoroscopy time from venous access until first pacing threshold for all RV Sheath patients (n = 15) was 81 ± 36 seconds compared to 81 ± 78 seconds for standard sheath patients (P = NS). For successful RV Sheath patients (n = 13), the fluoroscopy time until first pacing threshold was 77 ± 35 seconds (P = NS compared to standard sheath patients) Time from venous access until ventricular lead suturing for the RV Sheath patients (n = 15) was 500 ± 249 seconds compared to 480 ± 223 seconds for standard sheath patients. For successful RV Sheath patients (n = 13), time until ventricular lead suturing was 494 ± 262 seconds (P = NS for all comparisons). Fluoroscopy time from venous access until ventricular lead suturing was 227 ± 177 seconds for RV Sheath patients (n = 15) compared to 170 ± 109 seconds for standard sheath patients (P = NS). Fluoroscopy time from venous access until ventricular lead suturing for successful RV Sheath patients (n = 13) was 228 ± 184 seconds (P = NS).

	Pacing Treshold (V)	R-Wave (mV)	Impedance (Ohm)
RV Sheath	0.3 ± 0.1	15.6 ± 5.5	1075 ± 163
Standard	0.4 ± 0.2	16.1 ± 5.9	987 ± 191

Table 2. Acute Lead Data (P = NS for all comparisons).

Acute lead data are shows in Table 2. The acute ventricular pacing thresholds were not significantly different between the two groups: Pacing threshold for the RV Sheath group was 0.3 ± 0.1 volts compared to standard sheath pacing threshold of 0.4 ± 0.2 volts. Measured R-waves were nearly identical at 15.6 ± 5.5 volts for the RV Sheath group compared to 16.1 ± 5.9 volts for the standard sheath cohort. Lead impedance values were similar, as well, at 1075 ± 163 ohms for the RV Sheath group compared to 987 ± 191 ohms for the standard sheath group (P = NS).

There were no complications during the study. Specifically, no ventricular arrhythmias were provoked, there was no case of RV perforation from the RV Sheath, and there was no excessive bleeding.

Discussion

Permanent transvenous pacemaker leads were first implanted directly by isolating the cephalic vein, performing a venotomy, and advancing the pacing lead through the venotomy into the venous circulation. Since Littleford published his landmark article [4] in 1979 describing the use of an introducer sheath to pass the pacing lead directly into the subclavian vein, there has been a continual shift toward more use of the subclavian vein introducer sheath technique. The growth of dual chamber pacing requiring the placement of two leads has furthered that trend since it is often not possible to pass two pacing leads through the cephalic vein. Other than the addition of a hemostatic valve to the introducer sheath [5], there has been little if any evolution in the generally accepted, widely used technique for introducing pacing leads since Littleford's publication of the introducer sheath technique in 1979.

The lack of innovation no doubt is due in part to the relative ease in which pacing leads can be manipulated into the RV in most, though clearly not all, procedures. Various obstacles to lead placement can at times make lead positioning difficult in the hands of even the most experienced operator. Moreover, it has been estimated that more than 80% of pacemaker implantation procedures are performed by low volume operators performing less than 40 implants per year. Complication rates are particularly high when procedures are performed by operators performing less than 12 implants per year [6]. Difficulties negotiating tortuosity in the subclavian vein or even in the SVC can be time-consuming. Problems crossing the TV can often require either prolapsing the lead or trying various stylet curves until the valve is finally negotiated. Inadvertent placement of the lead in the coronary sinus is usually, but not always, apparent radiographically but sometimes requires a lateral fluoroscopic view to be certain.

The RV Sheath is capable of overcoming virtually all of these obstacles. The long sheath advanced over the wire, and eventually over the flotation catheter, avoids the problem of manipulating a tined pacing lead through a tortuous venous system. The tricuspid valve is easily crossed with the flow-directed balloon-tipped catheter and the introducer sheath is advanced easily over the flotation catheter into the RV. The pacing lead may be advanced directly to the RV apex through the sheath thus avoiding all problems with venous tortuosity and tricuspid valve interaction. The coronary sinus is avoided by the flow-directed property of the flotation catheter.

The present study demonstrates the feasibility of the RV Sheath technique for pacemaker lead implantation. The present study did not demonstrate more rapid placement of the ventricular pacing lead compared to the standard introducer sheath technique. However, these initial 15 patients in the RV Sheath group represent "learning curve" patients as no RV Sheath procedures were performed prior to these 15 implants. It is therefore possible that with further experience, the time required for the technique may decrease. Furthermore, the procedures were performed using an "off the shelf" long peel-away introducer sheath. Much of the procedural time associated with RV Sheath use was due to the slow process of carefully peeling away the sheath while maintaining the pacing lead fixed in position. A lubricious inner coating on the introducer sheath and a "slit-away" mechanism rather than a peel-away mechanism would likely decrease procedure time considerably. Additionally, the introducer sheath used in this study was of uniform thickness and flexibility. Ideally, a sheath of variable flexibility being firmer more proximally and softer and more atraumatic distally would be desirable. A kink-resistant material would also improve procedural success as two patients failed to have their pacing leads delivered to the RV due to kinking of the sheath at the level of the TV. Such kink-resistance would also be important if the RV sheath were advanced from the right subclavian vein rather than from the left side due to the more acute angle of the right subclavian vein into the SVC compared to the less acute angle when approaching from the left subclavian vein.

Use of the RV Sheath potentially could facilitate the placement of both larger and smaller pacing leads. The larger leads employed for transvenous implantable cardiodefibrillator devices (ICD) are significantly more difficult to position than standard pacing leads. ICD leads typically cannot be prolapsed across the TV and are often difficult to manipulate to the RV apex which is usually required to obtain satisfactory defibrillation thresholds. The RV Sheath may be ideally suited for the delivery of ICD leads to the RV apex, although no studies have been done to date with this technique. Conversely, the RV Sheath may make it possible to develop and deliver significantly smaller diameter pacing leads [7] to the RV apex than are currently possible since extensive lead manipulation would no longer be required.

If the RV Sheath can be refined such that ventricular pacing leads can be placed more quickly and more safely than when the conventional technique is used, there would be both quality of care and economic benefit. Operating room time could be decreased, and patient and staff exposure to fluoroscopic radiation could be minimized. Importantly, the occasional time-consuming process of negotiating venous tortuosity or a difficult-to-cross TV could potentially be avoided even by low-volume operators by the advantages offered by the RV Sheath.

Conclusions

Initial experience with ventricular pacing lead placement using a RV Sheath advanced over a balloon flotation catheter is encouraging. Despite the absence

of any prior experience with this method and the use of a relatively crude prototype RV Sheath, there were no procedural complications and the total time and fluoroscopy time required for lead placement with the RV Sheath were not significantly different than that required for procedures utilizing a standard, short introducer sheath. Acute pacing and sensing thresholds obtained using the RV Sheath system were excellent and equivalent to those obtained using the standard introducer system. This early experience suggests that the RV Sheath may be a superior method to currently used techniques for placement of pacing leads in the RV, particularly for low-volume operators who perform the majority of pacemaker implantation. The results of this study suggest the need for several RV Sheath modifications including a more lubricious inner coating, variable flexibility, a slit-away rather than peel-away mechanism, and a more kink-resistant design. In addition to facilitating placement of conventional ventricular pacing leads, potential future applications of the RV Sheath include placement of ICD leads and placement of ventricular pacing leads smaller than those currently available.

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