First-in-human case of repeat pulmonary vein isolation by targeting visual interlesion gaps using the direct endoscopic ablation catheter after single ring pulmonary vein isolation

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Introduction

Gaps between radiofrequency (RF) ablation lesions are the culprits for failed pulmonary vein isolation (PVI) leading to recurrent atrial arrhythmias. The ability to directly visualize in real time and eliminate interlesion gaps may improve the success of RF ablation by achieving contiguous linear ablation lesion sets. We aimed to describe to the best of our knowledge the first reported clinical case using the direct endocardial visualization (DEV) ablation catheter (Voyage Medical Inc., Redwood City, CA) to successfully reisolate pulmonary veins (PVs) by visually targeting interlesion gaps under direct endoscopic visualization during a clinical trial undertaken at our institution.

The DEV catheter uniquely delivers RF energy using the virtual electrode.[1] The virtual electrode can be conceptualized as the intervening saline column within the hood aperture in contact with the endocardial surface, thus preserving visualization of the target endocardium during ablation. The fiberscopic camera is located at the distal hood to visualize the endocardial surface as blood is purged away by the saline irrigation to create an unobstructed field of view (FOV).[1]

Case report

A 60-year-old man with recurrent drug-refractory symptomatic paroxysmal atrial fibrillation (AF) was referred for repeat PVI. His debilitating symptoms had returned despite multiple electrical cardioversions and pharmacologic therapies necessitating a repeat ablation. He had a mildly dilated left atrium (LA) and normal left ventricular systolic function. An initially successful single-ring PVI ablation had been performed 6 months earlier using a conventional irrigated-tip catheter.[2]

KEYWORDS Ablation technology; Direct endocardial visualization catheter; Ablation catheter; Virtual electrode; Atrial fibrillation; Atrial arrhythmia; Pulmonary vein isolation; Interlesion gap; Radiofrequency ablation; Electroanatomic mapping

ABBREVIATIONS **AF** = atrial fibrillation; **DEV** = direct endocardial visualization; **EAM** = electroanatomic; **EGM** = electrogram; **FOV** = field of view; **IR** = infrared; **LSPV** = left superior pulmonary vein; **NFUS** = near-field ultrasound; **PV** = pulmonary vein; **RF** = radiofrequency; **VGLA** = visually guided laser ablation

(Heart Rhythm Case Reports 2015;1:279–284)

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Ablation procedural details

An 8.5Fr medium-curve Agilis sheath and 8.5Fr SL1 guiding sheath were used to perform double transseptal punctures using a Brockenbrough needle. The Agilis was upgraded to a 14Fr sheath to accommodate the DEV catheter. The 3-dimensional electroanatomic (EAM) geometry was created using NavX (St. Jude Medical Inc., St. Paul, MN) and Lasso catheters at baseline in order to subsequently validate the map created by the direct visualization catheter. Activation mapping was performed using the 4 metal plate contact electrodes configured to provide 4 pairs of contact bipolar electrograms (EGMs) across the distal hood face apposed to the endocardial surface. Online Supplemental Movie 1 is a fluoroscopic recording in the right anterior oblique view of the circular mapping catheter (Halo, Biosense Webster Inc., Diamond Bar, CA) positioned in the left superior pulmonary vein (LSPV) and the DEV catheter positioned close to the ostium of the LSPV. A 5-mm decapolar catheter was positioned in the coronary sinus. A temperature probe was used to monitor esophageal temperature during ablation.

PVI using the DEV ablation catheter integrated with 3-dimensional EAM and bipolar EGMs

Figure 1 shows the FOV through the DEV catheter (2.8-mm central hood aperture and 6.8-mm diameter) to enable visual mapping of the anatomic gap. An activation map of the LA created using the contact bipolar EGMs of the DEV catheter revealed earliest competing activation on the mid-posterior LA wall.

http://dx.doi.org/10.1016/j.hrcr.2014.12.009

KEY TEACHING POINTS

- Direct Endoscopic Ablation Catheter utilized a fiberscopic camera at the distal hood to visualize endocardial surface as blood is purged away by the saline irrigation to create an unobstructed field of view (FOV).
- Real-time full-color direct endocardial visualization of partially or non-ablated inter-lesion gaps associated with contact bipolar EGM signals of surviving myocardium was clinically feasible. Electrically reconnected gaps were visually and electrically mapped.
- Electrically reconnected visual gaps were successfully ablated by delivering radiofrequency energy using the virtual electrode under visual guidance that resulted in electrical re-isolation of the pulmonary veins and posterior left atrium following prior single ring pulmonary vein isolation procedure.

Visual mapping of the anatomic gap correlated with earliest electrical conduction into the single ring.

The activation map showed the earliest competing activation represented by the white strip was located on the mid-posterior LA wall. This was targeted first and ablated under visual guidance. After abolition of the visual gap, the next earliest breakthrough was localized to the anterior aspect of the left PV/left atrial appendage (LAA) ridge. The fractionated PV potentials recorded by the hood-face electrodes at the ridge suggested a region of electrically reconnected tissue (Figure 2A). EGMs recorded in this region correlated with the visually pink gap of residual viable endocardium as seen through the FOV (see Online Supplemental Movie 2). This was characteristic for an electrically reconnected anatomic gap on the old ablation line flanked by regions of old electrically inert ablated scar. Chronically ablated scar appeared as white endocardial tissue through the FOV over the left PV ridge (Figure 2B).

Abolition of visual gap by RF ablation delivered via the virtual electrode successfully electrically reisolated both sets of PVs

RF ablation lesions were delivered via the virtual electrode of the DEV ablation catheter targeting the visual anatomic gap with the earliest fractionated EGM signals. A Stockert RF generator (Biosense Webster) was used to deliver RF power titrated from 7 W up to 15 W for durations of 20 to 40 seconds. A saline irrigation rate of 10–15 mL/min was used during visual mapping, and a higher irrigation rate of 25 mL/min was delivered during ablations using the CoolFlow pump (Biosense Webster).

Figure 2 highlights the real-time correlations between (1) direct full-color endoscopic visualization of the pink inter-lesion gap between ablated tissue; (2) bipolar EGMs recorded at the gap indicative of electrical conduction and tissue viability; and (3) ablation lesions delivered by the DEV catheter localized on the NavX EAM map. When interpreted in conjunction, these images were helpful in the guidance and delivery of RF energy at the targeted gap to successfully electrically reisolate the PVs as well as the posterior LA wall.

Confirmation of PVI with dissociated signals and differential pacing in the LAA confirming far-field appendage signals

Figure 3A shows the absence of EGM from the DEV catheter positioned within the LSPV, confirming successful reisolation. The acutely blanch whitish appearance of the ablated gap at this location after electrical reisolation as seen through the FOV is represented (Figure 3A). The patient reverted to normal sinus rhythm during ablation at the LSPV/LAA ridge. At 12-month follow-up, the patient remained asymptomatic and had documented arrhythmia-free 7-day Holter monitoring.

Discussion

Voyage IRIS DEV ablation catheter

Voyage Medical Inc was a startup company founded in late 2006. It received 3 rounds of venture funding through 2012. The initial funding was in support of a system developed to guide transseptal puncture under direct visualization.[3] This

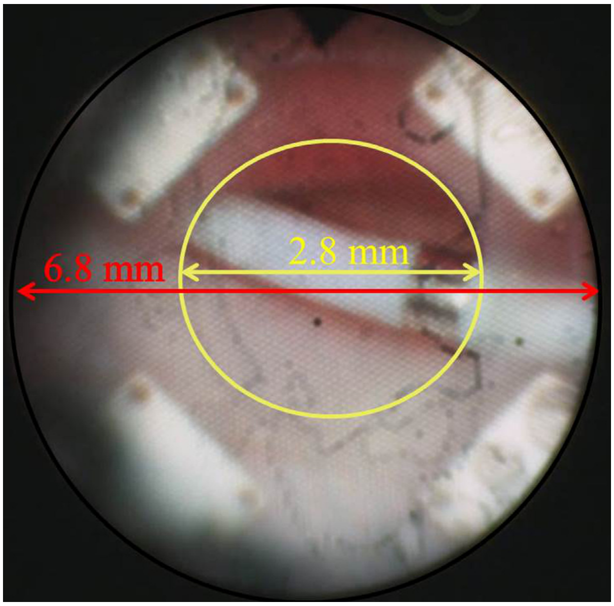

Figure 1 Field of view (FOV) through the direct endocardial visualization catheter measuring 2.8 mm across the central hood aperture and 6.8-mm-diameter hood face. The FOV facilitates visual mapping for the anatomic gap of electrical reconnection embedded in the region of earliest activation. Local endocardial tissue electrogram (EGM) signals were recorded by 4 metal-plate contact electrodes situated on the hood face. The electrodes were configured by an EP recording system (Prucka) to provide 4 pairs of contact bipolar EGMs across the hood face and displayed on the EP recording system (Prucka). A Lasso electrode is seen in contact with the left superior pulmonary vein tissue in the FOV.