CLINICAL STUDY

Idiopathic Ventricular Arrhythmia Ablation Using Non-Fluoroscopic Catheter Visualization System

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Summary

A novel, sensor-based, electromagnetic, non-fluoroscopic catheter visualization (NFCV) system shows tracked catheters directly on pre-acquired fluoroscopy or cine loops. We aimed to evaluate the effectiveness of this system in the setting of catheter ablation for idiopathic premature ventricular contractions/ventricular tachycardia (i-PVC/VT).

A total of 30 i-PVC/VT ablation procedures were performed using the NFCV system in conjunction with three-dimensional electroanatomic mapping system (3D-EMS) between January 2013 and April 2017. At the beginning of the procedure, cine loops of right and left anterior oblique views were obtained and replayed for subsequent mapping and ablation. Right ventriculography, aortography, or coronary angiography was performed, depending on the chamber of interest. We reviewed procedural parameters, comparing with the i-PVC/VT ablation procedure using conventional fluoroscopy (CvF) system (pre-, and post-NFCV implementation; 20 and 11 cases, respectively).

I-PVC/VTs were successfully eliminated in 26 patients (87%) in the NFCV group and in 26 (84%) in the CvF group (P = 1.000). The procedure time in the NFCV group was comparable to that in the CvF group (119.8 versus 125.0 minutes, respectively, P = 0.868); the total fluoroscopy time was significantly shorter in the NFCV group (3.3 versus 16.6 minutes, P < 0.001). One patient in the CvF group experienced cardiac tamponade, requiring pericardial drainage. No major complications were encountered in the NFCV group.

NFCV system, in conjunction with 3D-EMS, was safe and feasible for i-PVC/VT mapping and ablation. The system contributed to dramatically reduced fluoroscopy time, compared with CvF.

Key words: Idiopathic premature ventricular contraction, Idiopathic ventricular tachycardia, Radiation exposure, MediGuide

For decades, fluoroscopy has been a fundamental imaging technology used during invasive cardiovascular procedures, including catheter ablation and device implantation. In light of the growing awareness of the risks associated with medical radiation, current guidelines strongly emphasize the importance of performing catheter procedures based on the “as-low-as-reasonably-achievable” principle. 3D-EMS have been widely used, contributing to reduced radiation exposure during catheter ablation. Radiation exposure, however, remains a serious problem both for patients and physicians due to increasing procedure complexity.

A novel, sensor-based, electromagnetic, non-fluoroscopic catheter visualization (NFCV) system, MediGuide (Abbott, Chicago, IL) was recently introduced and allows visualization of tracked catheters directly on fluoroscopy or cine loops acquired at the beginning of a procedure, without the need for live x-rays. Experience using NFCV system-guided ablation targeting supraventricular tachycardia, atrial flutter, and atrial fibrillation has demonstrated safe and feasible outcomes, with much less fluoroscopy time and radiation than conventional fluoroscopy (CvF) system-guided ablation.

Idiopathic premature ventricular contraction/ventricular tachycardia (i-PVC/VT) is one of the arrhythmias frequently encountered in daily practice and is generally considered to have a benign prognosis. I-PVC/VT can, however, cause severe symptoms or lead to impaired ventricular (LV) systolic function when its burden is high; catheter ablation is recommended in such cases. The majority of i-PVC/VT originates from the right ventricular outflow tract (RVOT), aortic sinus of Valsalva (ASV), or...
left ventricular outflow tract (LVOT); therefore, the positional relationship between the exact ablation site and the anatomical structures, especially coronary artery ostia, must be clearly recognized.

In July 2015, the NFCV system was introduced to our institute. We speculated that i-PVC/VT mapping and ablation would greatly benefit from the use of this system. We reviewed our initial experience with NFCV-guided i-PVC/VT ablation procedures and compared them with those performed before implementing the NFCV system.

Methods

Study design: A total of 30 consecutive i-PVC/VT ablation procedures using the NFCV system were performed between July 2015 and April 2017 (NFCV group). Data on patient demography, preoperative testing, ablation outcomes, and procedural parameters were collected. We compared these data with those from consecutive 31 i-PVC/VT ablation procedures performed with CvF systems (CvF group) (Axiom Artis BC™, Siemens, Forchheim, Germany or INFX-8000V™, Toshiba, Tokyo, Japan) of which 20 procedures were performed before NFCV implementation during the period of January 2013 to June 2015 and 11 were performed after NFCV implementation from July 2015 to April 2017. Eleven patients underwent the procedure in the room without NFCV due to the procedure scheduling. All ablation procedures in the CvF and NFCV groups were performed by either of two experienced operators (AU or YM). Fluoroscopy time was used to compare radiation exposures, as the comparison of the radiation doses and dose-area products were considered inappropriate due to the different fluoroscopic systems used in each group. Written informed consent was obtained from all patients prior to their procedures, and the study was approved by our institutional review board.

Description of NFCV technology: As previously described, the NFCV system has three components: a transmitter within the fluoroscopy detector of a conventional flat panel x-ray imaging system (Artis™ zee angiography system [Siemens]), a miniature (<1 mm) locator sensor within the distal end of a specialized catheter, and an electromagnetic field sensor attached to the patient’s chest. The transmitter generates a 3D electromagnetic field aligning the fluoroscopy space with the 3D magnetic sensor field. Therefore, a sensor-equipped catheter can be tracked non-fluoroscopically using an identically positioned marker and the electromagnetic sensor field. Cardiac cycle-dependent changes in the catheter position are adjusted by matching the replay speed of the cine loops with the real-time electrocardiogram (ECG) signal. The chest sensor works as an anchor for the system, and continuously scans the patient’s position within the tracking space. It also provides information regarding respiration and patient or table movement, so the system can compensate and accurately display the catheter position. When used concomitantly with 3D-EMS (EnSite Velocity™, Abbott), the NFCV system can offer electromagnetic catheter localization with more precise field scaling than the conventional EnSite algorithm. Additionally, when using MediGuide-enabled catheters as the positional references for EnSite Velocity, catheter shifts or displacements can be corrected.

Procedure set-up and workflow: A 12-lead ECG of the target i-PVC/VT was obtained at the beginning of each procedure and stored on the EP Lab system (CardioLab, GE Healthcare, Wilmington, MA). All procedures were performed under mild conscious sedation, using dexmedetomidine hydrochloride and fentanyl, and continuous invasive arterial blood pressure monitoring. If the frequency of spontaneous i-PVC/VT dramatically decreased during the procedure, we reduced or discontinued the sedatives and isoproterenol (0.5-2.0 μg/minute) infusion or epinephrine bolus injection was attempted. Burst pacing at a cycle length of up to 250 ms was also attempted from the RV apex.

Vascular access was gained via the left femoral vein and a sensor-guided or conventional diagnostic catheter (NFCV group, MediGuide-Enabled Livewire™ Catheter, Abbott; CvF group, EP star, Japan Lifeline, Tokyo, Japan) was advanced to the RV apex. In the NFCV group, cine loops at the right anterior oblique (RAO) (30°) and left anterior oblique (LAO) (60°) views were obtained and stored in the NFCV system, in advance. Thereafter, a diagnostic catheter was introduced with the catheter tip being visualized on the stored images. If the origin was considered to be the ASV or LVOT, another luminal decapolar electrode catheter (Inquiry™ Luma-Cath™, Abbott) was positioned in the coronary sinus (CS). Then, a 1.4 Fr octapolar catheter with a 5-mm interelectrode spacing (EP star, Japan Lifeline) was advanced into the luminal catheter to record the activation from the anterior interventricular vein. Based on the acquired i-PVC/VT ECG morphology and the activation timing from the diagnostic catheters, the initial chamber to be mapped was determined.

For mapping and ablation, an 8-Fr sheath was introduced, via the right femoral vein or the femoral artery, and a MediGuide-enabled, bi-directional, irrigated ablation catheter (MediGuide™ Enabled Safire Duo™ Catheter, Abbott) was advanced to the chamber of interest, in NFCV patients. For the index 13 procedures, right ventriculography (RVG) was performed before mapping and used as the background image (Figure 1A, B). When the target chamber was the ASV, aortography (AOG) or right and the left coronary angiography (CAG) was performed and stored in the NFCV system (Figure 1C, D). In the CvF group, a bidirectional, irrigated ablation catheter (Navistar Thermocool, Navistar Smart Touch, Biosense Webstar, Diamond Bar, CA, USA or Ablaze Fantasista, Japan Lifeline) was introduced into the target chamber. The latter 10 cases in the NFCV-group and 2 in the CvF group performed RVOT mapping using the Auto-map™ system with multipolar catheter. In both groups, activation and pace mapping were performed in conjunction with 3D-EMS (EnSite Velocity™, Abbott or CARTO3, Biosense Webstar). Although the EnSite system was exclusively used for the NFCV group, the selection was based on physician preference in the CvF group. Procedure workflows are demonstrated in Figure 2.

Radiofrequency (RF) application: RF energy (maximum power, 35 W; irrigation flow, 17 mL for 60-90 seconds) was applied when the distal bipolar electrode pair of the
ablation catheter showed the earliest activation, preceding the onset of the QRS wave, with the sharp QS pattern at the distal unipolar recording. In addition, good pace matching was a marker for the ablation target site. When mapping in either the RV or ASV failed to detect an appropriate site for RF application, nearby structures (ASV, LVOT for RV outflow; LVOT and RVOT for ASV) were also mapped. In the NFCV group, RF application in the ASV was attempted only when the distance between the real-time visualized catheter tip and the coronary artery ostium on the pre-acquired image was ≥ 10 mm. In the CvF group, when the target site was in the left or right coronary cusp, the ablation catheter was withdrawn, and CAG was performed prior to RF delivery. Procedural success was defined as the absence of spontaneous or induced target i-PVC/VT at the end of the procedure, with or without isoproterenol and/or epinephrine administration, and no spontaneous target i-PVC/VT during the subsequent overnight ECG monitoring.

**Statistics:** In the CvF group, 2 patients underwent a second procedure after the failed index procedure. The demographic data for these patients were analysed using only the data for the index procedure. Both the index and second procedural data were used for the analysis, since each procedure was assumed to be independent. Categorical data were described as the actual number or percentage. Numeric data were described as medians and the first and third interquartile ranges (1st and 3rd IQRs), for skewed variables, and means and standard deviations (SDs) for non-skewed variables. Comparisons between two groups were performed using the Mann-Whitney test for skewed data and Student’s t-test for non-skewed data. To compare
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![Diagram of procedural workflows in the non-fluoroscopic catheter visualization (NFCV) and conventional fluoroscopy (CvF) groups.]

Figure 2. Procedural workflows in the non-fluoroscopic catheter visualization (NFCV) and conventional fluoroscopy (CvF) groups.

categorical data, Fisher’s exact or chi-square tests were used. A $P$-value $< 0.05$ was considered statistically significant. EZR version 1.35 was used for the statistical analyses.\(^{15}\)

**Results**

**Patient characteristics:** In both groups, the number of female patients was slightly dominant (Table I). The pre-procedural PVC burdens, chamber sizes, ejection fractions, and body status were comparable between the NFCV and CvF groups.

**Procedural parameters:** Procedural parameters are shown in Table II. The number of mapped chambers was greater in the NFCV group. RVG was exclusively performed in the NFCV group. AOG or CAG was performed in all NFCV patients requiring ASV mapping ($n = 14$) and in all CvF patients requiring ASV ablation ($n = 5$). The total number of diagnostic catheters was comparable between the groups ($P = 0.385$). There was no significant difference in total procedure time between the groups (NFCV, 119.8 minutes; CvF, 125.0 minutes; $P = 0.868$). Total fluoroscopy time, however, was significantly shorter in the NFCV group (3.3 minutes) than in the CvF group (16.6 minutes; $P < 0.001$). One patient in the CvF group experienced cardiac tamponade resulting in pericardial drainage. There were no procedural complications in the NFCV group. The procedural success rates were similar for the NFCV (87%) and CvF (84%, $P = 1.00$) groups. In the CvF group, EnSite Velocity was used in 2 patients and CARTO3 was used in the rest of the group.

In the CvF group, although the RAO view (10.4 minutes) was more frequently used than the LAO view (3.9 minutes), the radiation doses (37.2 mGy versus 43.8 mGy, respectively) and dose-area products (361.7 mGym\(^2\) and 414.6 mGym\(^2\), respectively) were greater in the LAO view, as expected.

There were no significant differences in procedure time and total fluoroscopy time between the CvF groups before- and after NFCV implementation (data not supplied).

**NFCV contribution to multi-chamber mapping and ASV mapping/ablation:** Figure 3 shows the fluoroscopy time in both groups. A statistical analysis of the learning curve was not performed because of the small number of patients in the NFCV group. The fluoroscopy time in the initial NFCV patient, however, was only 1.9 minutes, followed by 0.5 and 2.5 minutes in the 2 subsequent patients, suggesting that the system could be used with a minimal learning curve for this type of ablation. Patients in the NFCV group requiring fluoroscopy time ≤ 5 minutes underwent ASV mapping or mapping of more than 2 chambers. To evaluate the impact of ASV and/or multi-chamber mapping on fluoroscopy times, a comparative statistical analysis was performed. In the CvF group, there were significant differences in fluoroscopy times between procedures with and without ASV mapping (Figure 4A; mean fluoroscopy time 31.9 minutes for procedures involving ASV mapping versus 14.2 minutes for those without ASV mapping, $P = 0.045$). In contrast, the difference was not statistically significant in the NFCV group (2.5 minutes versus 4.0 minutes, $P = 0.28$). Similarly, multi-chamber mapping resulted in significantly longer fluoroscopy times in the CvF group (Figure 4B; 29.4 minutes for
multi-chamber mappings versus 14.2 minutes for single-chamber mappings, $P = 0.005$), but the difference did not reach statistical significance in the NFCV group (2.5 minutes versus 3.8 minutes, $P = 0.371$). The NFCV system reduced fluoroscopy time by 86.4% in procedures involving ASV mapping and by 71.8% in those without ASV mapping. The system also reduced fluoroscopy time by 86.4% in procedures involving ASV mapping and by 71.8% in those without ASV mapping. 

### Discussion

**NFCV system contribution:** I-PVC/VT ablation was safely performed using the NFCV system, with very short fluoroscopy time, leading to feasible outcomes and no observed procedural complications. This is the first study reporting the safety and benefits of NFCV in ablation for ventricular arrhythmias in which catheter position must be carefully appreciated on the angiography. Previously, dramatic reduction in radiation exposure associated with supraventricular tachycardia, atrial flutter, and atrial fibrillation ablation procedures have been reported, corresponding with our results. Since i-PVC/VT patients are typically relatively young, minimizing fluoroscopy times is of great benefit. In our series, RVG, AOG, or CAG was attempted; NFCV, non-fluoroscopic catheter visualization; NSVT, non-sustained ventricular tachycardia; and VPC, ventricular premature contraction.

<table>
<thead>
<tr>
<th>Chambers mapped, $n$</th>
<th>NFCV group (n = 30)</th>
<th>CVF group (n = 31)</th>
<th>$P$ value</th>
</tr>
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<tbody>
<tr>
<td>Chambers ablated, $n$ (%)</td>
<td>RV 25 / ASV 15 / LV 5</td>
<td>RV 25 / ASV 8 / LV 4</td>
<td></td>
</tr>
<tr>
<td>Mapped chambers, $n$</td>
<td>1.0 (1.0–2.0)</td>
<td>1.0 (1.0–1.0)</td>
<td>0.022</td>
</tr>
<tr>
<td>Diagnostic catheters, $n$</td>
<td>1.0 (1.0–3.0)</td>
<td>1.0 (1.0–2.0)</td>
<td>0.385</td>
</tr>
<tr>
<td>CS catheters, $n$ (%)</td>
<td>11 (37)</td>
<td>7 (23)</td>
<td>0.27</td>
</tr>
<tr>
<td>RVG, $n$ (%)</td>
<td>13 (43)</td>
<td>0</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>AOG or CAG, $n$ (%)</td>
<td>14 (46)</td>
<td>5 (17)</td>
<td>0.025</td>
</tr>
<tr>
<td>Total procedure time, minutes</td>
<td>119.8 (76.0–226.0)</td>
<td>125.0 (90.0–202.5)</td>
<td>0.868</td>
</tr>
<tr>
<td>Total fluoroscopy time, minutes</td>
<td>3.3 (1.6–7.6)</td>
<td>16.6 (10.4–25.8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total radiation dose, mGy</td>
<td>22.8 (9.4–40.0)</td>
<td>90.9 (46.9–163.0)</td>
<td></td>
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<tr>
<td>Total dose-area product, mGym$^2$</td>
<td>219.1 (66.8–405.5)</td>
<td>834.4 (485.0–1376.5)</td>
<td></td>
</tr>
<tr>
<td>Procedural successes, $n$ (%)</td>
<td>26 (87)</td>
<td>26 (84)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Values are expressed as means ± SD, medians (1st-3rd interquartile range) or actual numbers and percentages. BMI indicates body mass index; BSA, body surface area; CVF, conventional fluoroscopy; LVDd, left ventricular end-diastolic dimension; LVDs, left ventricular end-systolic dimension; LVEF, left ventricular ejection fraction; NFCV, non-fluoroscopic catheter visualization; NSVT, non-sustained ventricular tachycardia; and VPC, ventricular premature contraction.
Figure 3. Fluoroscopy times in the conventional fluoroscopy (CvF) and non-fluoroscopic catheter visualization (NFCV) groups. The patient numbers represent their chronological order. Asterisks (*) indicate patients undergoing multi-chamber mapping and/or mapping/ablation at the aortic sinus of Valsalva.

Figure 4. Comparison of fluoroscopy times. A: Fluoroscopy times in the non-fluoroscopic catheter visualization (NFCV) and conventional fluoroscopy (CvF) groups, with and without aortic sinus of Valsalva (ASV) mapping. ASV mapping significantly prolonged fluoroscopy times in the CvF group, but not in the NFCV group. B: Fluoroscopy times in NFCV and CvF groups involving single- or multi-chamber mapping. Although multi-chamber mapping significantly prolonged fluoroscopy times in the CvF group, such a trend was not evident in the NFCV group.

In our study, 3D-EMS was used in conjunction with the NFCV system, in all patients. Sommer, et al. reported “conventional” supraventricular tachycardia ablation using the NFCV system without 3D-EMS.16) Indeed, 3D-EMS may not be necessary in relatively simple ablation procedures. In our series, we used 3D-EMS for tagging good and poor pace map sites or showing activation timing. By using the electromagnetic information from the NFCV system, the 3D-EMS impedance-based field is improved.

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Fluoroscopy times in the conventional fluoroscopy (CvF) and non-fluoroscopic catheter visualization (NFCV) groups. The patient numbers represent their chronological order. Asterisks (*) indicate patients undergoing multi-chamber mapping and/or mapping/ablation at the aortic sinus of Valsalva.

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which is another strength of this combination.

Regarding procedure time, there was no significant difference in total procedure time between the groups, which suggests a very limited learning curve. One explanation may be that the major factor that impacts procedure time in this type of ablation is the frequency of target i-PVC/VT during the procedure. Mapping time can be prolonged when the target VPC is less frequent, which is independent of the use of fluoroscopy. Use of more recent 3D-EMS that enables multipoint acquisition and automated annotation, can reduce mapping time but future analysis is required. Another possible reason for the comparable procedure time is, ablation-refractory PVC. Some i-PVC/VT were temporarily suppressed by RF application but recurred shortly after the application. In such cases, RF application time could be long and ablation from multi-chamber is necessary, resulting in longer procedure time.

Other low fluoroscopy techniques: Three-dimensional-EMS with pre-acquired computed tomography (CT) image integration can provide relatively accurate anatomical information for real-time catheter mapping. Yamashita, et al. recently reported the feasibility of CT image registration in conjunction with 3D-EMS to minimize coronary artery injury in patients undergoing epicardial VT ablation.20 They noted, however, that concomitant CAG underestimated the distance between the ablation sites and the real position of the coronary arteries, determined using CT image integration; the registration error was 3.9 mm. In contrast, a recent report evaluating the accuracy of the MediGuide™ technology, using a phantom model, showed that the point localization (0.5 ± 0.3 mm) and catheter visualization (0.4 ± 0.1 mm) errors on the x-ray screen were below the clinically relevant threshold.21 From a safety standpoint, the NFCV system provided precise anatomical information. Pre-procedural CT scanning adds extra radiation exposure to the ablation procedure itself, but in our NFCV i-PVC/VT ablation procedure CT was unnecessary throughout the workflow.

Zhang, et al. reported that remote magnetic navigation (RMN) (Stereotaxis, St Louis, MO) technology allows a 50.5% reduction in patient radiation exposure during RVOT PVC/VT ablation procedures compared with conventional manual mapping.22 Approximately half of their cases, however, required crossing over to manual mapping during the procedure, and the success rate associated with using only the RMN modality was relatively low (8 of 15 procedures). Given that catheter manipulation is completely different from that in the conventional manual procedure, the RMN procedure takes longer, as reported in many previous studies.

CartoUniv™ (Biosense Webstar) is another module that can integrate electroanatomic mapping into fluoroscopic imaging, demonstrating feasible outcomes for various types of arrhythmia,23 including VT.24 Lau, et al. recently reported a case of successful ASV origin VT ablation using the system.25 Although the procedure, fluoroscopy times, and radiation doses were not provided in the report, their workflow seemed very similar to our NFCV procedure. Both systems allow minimal radiation exposure without much alteration of the conventional workflow.

One difference is that the MediGuide™ system allows adjustment of the background movie, depending on the heart rate, yielding accurate anatomical location determinations. Limitations and future insights: The number of patients in this study might be too small to conclude the superiority and safety of NFCV system-guided i-PVC/VT ablations. Given that the procedural workflow and catheter manipulation was similar to conventional ablation procedures, however, the system is unlikely to increase procedural risks. Also, any learning curve effect might not need to be considered since the NFCV system provided a remarkable reduction in fluoroscopy time, starting with the index cases.

Another possibility is that operators’ learning curve affected the results, since two thirds of procedures in CvF group were performed earlier. However, all procedures were performed by experienced operators, and the latter one-third of procedures in CvF-group was performed in the same period as NFCV-group. As stated in the result, there were no differences in fluoroscopy time before and after NFCV implementation in CvF-group. We believe that the impact of the operators’ experience on the result is very limited.

As for any retrospective study, the fluoroscopy systems used in the 2 groups were different and we were unable to directly compare radiation exposures (i.e., radiation dose and dose-area product). However, as we soon realized the patient benefit of using the NFCV system for this type of ablation procedure, conducting a prospective study to compare i-PVC ablations with and without the NFCV system seems unethical.

The current system can only visualize the tips of sensor-embedded catheters. Positioning of the sheath and catheter shaft still requires fluoroscopic confirmation for safety. Also, the currently available MediGuide-enabled diagnostic and mapping catheters are limited. Expanding the availability of appropriate catheters, sheathes, and other tools may lead to further reductions in radiation exposure.

Conclusion

The NFCV system, in conjunction with 3D-EMS, is safe and feasible for i-PVC/VT mapping and ablation. The system contributes to a significant reduction in fluoroscopy time.

Disclosures

Conflicts of interest: Akiko Ueda and Toshiaki Sato have endowments from Abbott and Biotronik. There is no other conflict of interest.

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