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ORIGINAL ARTICLE

Placement of catheters without magnetic sensors in the coronary sinus without fluoroscopic guidance: Feasibility and safety evaluation

Department of Cardiovascular Medicine, Graduate School of Medical Sciences, Kumamoto University, Kumamoto, Japan

Correspondence

Tadashi Hoshiyama, Department of Cardiovascular Medicine, Graduate School of Medical Sciences, Kumamoto University, 1-1-1 Honjo, Kumamoto 860-8556, Japan. Email: tadashi@kumamoto-u.ac.jp

Abstract

Background: A three-dimensional (3D) mapping system is essential to reduce radiation exposure during catheter ablation. When using the CARTO 3D mapping system, only the catheter with magnetic sensor can visualize its location. However, once target chamber matrix is created using the catheter, even the catheters without magnetic sensors (CWMS) can enable visualization. We aimed to investigate the feasibility and safety of placing a CWMS in the coronary sinus (CS) without fluoroscopic guidance.

Methods: The study group comprised 88 consecutive patients who underwent catheter ablation. CWMS placement was performed without fluoroscopic guidance in 47 patients and with fluoroscopic guidance in 41 patients. Placement without fluoroscopic guidance was performed after creating a visualization matrix of the CS, right atrium, and superior vena cava using a catheter with a magnetic sensor. Feasibility and safety were compared between the two groups.

Results: Successful catheter placement was achieved in all patients without fluoroscopic guidance, with no inter-group difference in the median procedure time: with guidance, 120.0 [96.0–135.0] min, and without guidance, 110.0 [97.5–125.0] min; p = .22. However, radiation exposure was significantly shorter, and the effective dose was lower without fluoroscopic guidance (0 [0–17.5] s and 0 [0–0.004] mSv, respectively) than with fluoroscopic guidance (420.0 [270.0–644.0] s and 0.73 mSv [0.36– 1.26], respectively); both p < .001.

Conclusions: CWMS placement without fluoroscopic guidance is feasible, safe to perform, and does not involve complications. Our technique provides an option to decrease radiation exposure during catheter ablation and electrophysiological testing.

KEYWORDS

catheter ablation, radiation exposure, three-dimensional mapping

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1 | INTRODUCTION

Information obtained from coronary sinus (CS) catheter electrograms is essential during catheter ablation or electrophysiological testing. Generally, the catheter is inserted into the CS under fluoroscopic image guidance.^{1,2} However, radiation exposure during catheter intervention increases the risk to the medical staff. In addition, this risk has shown to be associated with increasing catheter intervention cases.^{3,4} Although reducing radiation exposure has become possible with the use of three-dimensional (3D) mapping systems and intracardiac echocardiography,⁵ only a catheter with a magnetic sensor can be visualized under the CARTO 3D mapping system (Biosense Webster). However, some institutions select catheters without magnetic sensors (CWMS) as the CS catheter to prioritize defibrillation function, or for economic feasibility. On the other hand, it has been shown that a CWMS can be visualized following target chamber's matrix creation using a magnetic sensor catheter.⁶ Apart from this finding, however, no studies have so far evaluated the CWMS visualization, catheter manipulation feasibility, and safety without fluoroscopy under the CARTO system. If CS catheter placement is possible without fluoroscopy, radiation exposure during catheter ablation and electrophysiological testing can be reduced. Therefore, the aim of this study was to evaluate the feasibility and safety related to CS catheter cannulation of CWMS without fluoroscopy.

2 | MATERIALS AND METHODS

2.1 | Statement of ethics

The study protocol was approved by the Human Research Committee of Kumamoto University Hospital (approval number, Rinri 2329). An opt-out method was used for the consent.

2.2 | Study group

The study group included 88 consecutive patients who underwent catheter ablation for atrial fibrillation (AF). Patients were allocated to

two groups, one using CS catheter placement without fluoroscopic guidance (n = 47) and the other under conventional fluoroscopic guidance (n = 41). For all patients, antiarrhythmic drug treatment was discontinued for at least five half-lives prior to the procedure. Oral anticoagulation therapy was maintained for at least 1 month without interrupting warfarin therapy. Treatment with dabigatran, rivaroxaban, apixaban, and edoxaban was skipped only on the morning of the procedure.

2.3 | Catheter insertion into the CS

An 8-Fr intracardiac echocardiography catheter (SoundStar; Biosense Webster) was inserted into the right atrium via the right femoral vein. Before the transseptal puncture, a 6-Fr double decapolar steerable catheter (BeeAT; Japan Lifeline) was percutaneously inserted into the CS via the right jugular vein. In the present study, the subclavian vein and femoral vein were not used as the approach site.

Coronary sinus catheter placement without fluoroscopic guidance was performed according to the following three steps. In the first step, an anatomical mapping of the CS ostium was created using the CartoSound module of the CARTO 3 system (Biosense Webster), based on echo images. Zero correlation of the irrigation catheter was performed, after confirming that the distal tip was not contacting the tissue, under intracardiac echocardiography imaging (Figure 1). In the second step, fast anatomical mapping (FAM) and a 3D-virtual visualization matrix of the CS ostium, right atrium, and superior vena cava (SVC) were created using the irrigation catheter (ThermoCool SmartTouch SF catheter; Biosense Webster) via 8.5 Fr sheath steerable sheath (VIZIGO; Biosense Webster; Figure 2). In the third step, catheter placement into the CS was performed based on the previously created FAM (Figure 3).

For the conventional fluoroscopic guidance method, the catheter was inserted into the CS based on the real-time fluoroscopy images, without using 3D mapping and ultrasound images.

FIGURE 1 First step of the CS catheter placement. Left panel; Intracardiac echocardiography image during zero correlation of the irrigation catheter; the CS ostium was visible observed at the distal tip of the irrigation catheter. Right panel: 3D mapping image; the CS FAM was created after confirmation of the CS ostium on intracardiac echocardiography. CS, coronary sinus; FAM, fast anatomical map; LA, left atrium; RA, right atrium.





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FIGURE 2 Second step of the CS catheter placement, with the light green area indicating the visualization matrix. Left panel; 3D mapping image; the CS FAM was created using the irrigation catheter. Middle panel; creation of the CS and RA matrix. Right panel; creation of the SVC matrix. CS, coronary sinus; FAM, fast anatomical map; LA, left atrium; RA, right atrium; SVC, superior vena cava.



FIGURE 3 3D mapping image of the third step of the CS catheter placement, with visualization of the placement of the CWMS on 3D mapping. Left to right panels show the movement of the CS catheter to the CS. CS, coronary sinus; CWMS, catheter without magnetic sensor; RA, right atrium; SVC, superior vena cava.

2.4 | AF ablation procedure

Intravenous heparin was administered to maintain an activated clotting time of between 300 and 350s. Transseptal puncture was performed under intracardiac echocardiography imaging guidance. An 8.5-Fr long sheath (Daig SL-0; St. Jude Medical) and an 8.5-Fr steerable sheath (VIZIGO; Biosense Webster) were inserted into the left atrium. After transseptal puncture, left atrium FAM was created using a multipolar catheter (PENTARAY; Biosense Webster). Integration of CARTO images with computed tomography (CT) or magnetic resonance imaging (MRI) was performed based on the left atrial FAM image.

For patients undergoing the first session of catheter ablation, circumferential pulmonary vein (PV) isolation was performed by integrating the left atrial images using an irrigation catheter (ThermoCool SmartTouch SF catheter). SVC isolation was also performed, if an atrial potential was observed in the area. Linear ablation for the cavotricuspid isthmus (CTI) was performed only in patients with persistent AF. The procedure was completed after confirming the absence of non-PV foci. For patients undergoing a second or subsequent session of catheter ablation, ablation for the residual conduction gap was performed if the conduction gap of the prior procedure was observed. Non-PV foci ablation was also performed.

2.5 | Comparison of CS catheter placement with and without fluoroscopic guidance

The primary evaluation points were the feasibility and safety of the CS catheter placement. Feasibility was evaluated as the success rate of CS catheter placement without fluoroscopic guidance. The safety of the procedure was evaluated in terms of the complications involved in performing the procedures. The secondary evaluation points were the procedural time, patient's radiation exposure, and fluoroscopy time. Patient's radiation exposure was expressed as an effective dose (mSv). The effective dose was calculated based on the dose area product (DAP): (mSv = DAP [Gycm2] × 0.2).⁷ Measured outcomes were compared between the two groups, with and without fluoroscopic guidance.

2.6 | Statistical analysis

All continuous data were expressed as the median (interquartile range) owing to a skewed distribution using the Shapiro-Wilk test. Categorical variables were reported as a count (percentage). Differences between the two groups were evaluated using the Mann-Whitney *U* test for the continuous data. And, Fisher's exact test was used for the categorical data. *p*-value <.05 denoted a

TABLE 1 Characteristics of the study group

	All patients n: 88	Catheter placement conventional <i>n</i> : 41	Catheter placement without fluoroscopy <i>n</i> : 47	p-value
Age	70 (62–78)	70 (63–76)	67 (58-73)	.10
Male: n (%)	61 (69.3)	28 (68.3)	33 (70.2)	1.00
BMI (kg/m ²)	23.8 (21.9-26.1)	23.0 (21.5-26.2)	24.1 (23.3-25.9)	.15
BNP (pg/mL)	70.7 (26.2–123.4)	71.3 (22.7–122.0)	66.2 (31.8–127.4)	.84
EF (%)	58.9 (52.0-62.9)	57.6 (50.1-62.8)	60.3 (53.8-62.9)	.19
LADs (mm)	40.5 (37.4-44.6)	41.1 (37.9-43.2)	40.0 (36.3-45.0)	.97
eGFR (mL/min/1.73m ²)	62.0 (52.0-74.3)	61.0 (52.0-75.0)	64.0 (52.0-74.0)	.46
Cardiomyopathy: n (%)	18 (20.5)	9 (21.4)	9 (19.1)	.80
Second session: n (%)	9 (10.2)	4 (9.8)	5 (10.6)	1.00

Abbreviations: AF, atrial fibrillation; BMI, body mass index; BNP, brain natriuretic peptide; EF, ejection fraction; eGFR, estimated glomerular filtration rate; LAD, left atrial dimension.

TABLE 2 Procedural characteristics

1st session	All n: 58	Catheter placement conventional <i>n</i> : 28	Catheter placement without fluoroscopy <i>n</i> : 30	p-value
PV isolation: n (%)	58 (100)	28 (100)	30 (100)	NA
SVC isolation: n (%)	21 (36.2)	11 (39.3)	10 (33.3)	.79
CTI ablation: n (%)	28 (48.3)	12 (42.9)	16 (53.3)	.45
box isolation: n (%)	2 (3.4)	1 (3.6)	1 (3.3)	1.00
non PV foci ablation: n (%)	3 (5.2)	1 (3.6)	2 (6.7)	1.00
2nd session	All n: 8	Catheter placement conventional <i>n</i> : 4	Catheter placement without fluoroscopy <i>n</i> : 4	p-value
2nd session PV isolation: <i>n</i> (%)	All n: 8 3 (37.5)	•	•	p-value .14
		conventional <i>n</i> : 4	fluoroscopy n: 4	
PV isolation: <i>n</i> (%)	3 (37.5)	conventional <i>n</i> : 4 0 (0)	fluoroscopy n: 4 3 (75.0)	.14
PV isolation: n (%) SVC isolation: n (%)	3 (37.5) 3 (37.5)	conventional <i>n</i> : 4 0 (0) 1 (25.0)	fluoroscopy n: 4 3 (75.0) 2 (50.0)	.14 1.00

statistically significant difference between the two groups. All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria).

3 | RESULTS

3.1 | Characteristics of the study group

The characteristics of patients from our study group are summarized in Table 1. There were no differences between the two groups (with and without fluoroscopic guidance for CS catheter placement) in terms of age, the proportion of male patients, body mass index (BMI), brain natriuretic peptide (BNP), ejection fraction (EF), left atrial dimension (LAD), estimated glomerular filtration rate (eGFR), proportion of patients with cardiomyopathy, and the number of patients that underwent multiple sessions of AF ablation. The procedural characteristics are summarized in Table 2, with no inter-group differences.

3.2 | Primary points of evaluation

The CS catheter could be successfully visualized on the 3D mapping by creating a visualization matrix of the CS, right atrium, and SVC using a catheter with a magnetic sensor in the group without fluoroscopic guidance. The catheter was successfully inserted into the CS, without complications, in all cases. However, CS cannulation was hard to insert sufficiently in some cases due to the Thebesian valve. In these cases, the CS catheter was initially pulled back slightly and was subsequently adjusted in the direction or curve with reference to the CS FAM that was created by the ablation catheter. Following this method, CS cannulation was achieved in these cases. The median time for the three steps of CS catheter placement without fluoroscopic guidance was 234.0 (209.5-311.8) seconds. On the other hand, the median time for CS catheter placement under fluoroscopic guidance was 274.5 (188.3-426.8) seconds. There was no inter-group difference in the time required for CS catheter cannulation (p = .382). There were no complications associated with the procedure in either group.



FIGURE 4 Angiography image (left panel) and 3D mapping image (right panel) for a difficult case of CS catheter insertion; the yellow circle shows the CS ostium. CS, coronary sinus; LA, left atrium; RA, right atrium.

3.3 | Secondary point of evaluation

There was no inter-group difference in procedure time: without fluoroscopic guidance, 110.0 (97.5-150.0) min and with fluoroscopic guidance, 120.0 (96.0-135.0) min; p = .22. Also, no intergroup difference was observed with respect to the procedure time during PV isolation: without fluoroscopic guidance, 39.0 (35.0-43.0) min, and with fluoroscopic guidance, 43.5 (35.8-53.0); p = .08. The effective dose of radiation exposure was significantly lower in the group without fluoroscopic guidance (0 [0-0.004] mSv) than in the group with (0.73 [0.36–1.26] mSv) fluoroscopic guidance (p < .001). The fluoroscopy time required throughout the procedure was significantly shorter for the group without fluoroscopic guidance (0 [0-17.5] second) than in the group with (420.0 [270.0-644.0] second) fluoroscopic guidance (p < .001). And, the fluoroscopy time during CS cannulation without fluoroscopic guidance was zero in all patients, whereas the fluoroscopy time during CS cannulation under fluoroscopic guidance was obscure due to the retrospective nature of this study. During the 47 patients without fluoroscopic guidance, catheter ablation without fluoroscopy throughout the procedure was achieved in 30 patients.

3.4 | Other findings

Among the 88 patients forming the study group, SVC isolation was performed in 33 patients, with 18 of these patients being in the group without fluoroscopic guidance. As the FAM of the right atrium and SVC had already been created using an irrigation catheter, radiation exposure was not required during SVC isolation for these 18 patients.

3.5 | Case demonstration of a placement without fluoroscopy

Figure 4 shows CS catheter placement performed under fluoroscopic guidance in a complex case. A 66-year-old woman underwent catheter ablation for an uncommon flutter. Mitral valve replacement and tricuspid valve plasty had been performed 3 years prior for the treatment of severe mitral stenosis and tricuspid regurgitation. At that time, a maze procedure had also been performed for AF. During the first session of catheter ablation, a CS catheter was inserted into the CS without fluoroscopic guidance. Despite the changed anatomy due to the previous open-heart surgery, the CS catheter cannulation was successful and did not involve any complications. However, the patient required a second session of catheter ablation owing to the recurrence of the flutter. For the second session, CS catheter insertion was performed under fluoroscopic guidance. However, CS catheter placement was difficult because the anatomical location of the CS had changed as a result of the previous cardiac open-heart surgery. This resulted in insufficient insertion of the CS catheter (Figure 4). Therefore, catheter placement without fluoroscopic guidance may be a feasible option for patients with altered cardiac anatomy.

4 | DISCUSSION

LAO view

catheter

hottom

line of RA

4.1 | Main findings

There are three main findings of our study. First, placement of a CWMS without fluoroscopic guidance is feasible, with a low risk of complications. Second, this method significantly reduced radiation exposure, with no significant increase in procedural time. Third, CS catheter placement without fluoroscopic guidance may be one of the optional methods in patients with altered cardiac anatomy due to previous open-heart surgery.

4.2 | CS catheter placement without fluoroscopic guidance in the absence of magnetic function catheter

Coronary sinus catheter placement is required during AF ablation. Although a multielectrode catheter can differentiate a left PV potential from a left atrial appendage potential, CS pacing helps differentiate these potentials.¹ A CS catheter is also used as a reference catheter to identify non-PV foci.² Therefore, information obtained from CS catheter can be helpful during catheter ablation for AF. On the other hand, the time required for CS catheter cannulation varies, depending on the operators' experience and the patients' CS anatomy. Although reducing radiation exposure during catheter ablation and electrophysiological testing is important for both patients and the medical staff,^{3,4} the above facts may lead to increasing radiation exposure. It has been shown that intracardiac echocardiography and 3D mapping systems can help in this regard.^{7,8} However, only a catheter with magnetic sensor can be visualized under the CARTO 3D mapping system. Besides this, institutions have also been using CWMSs to prioritize the defibrillation function and reduce costs. Our findings show that a CWMS can be visualized in CARTO 3D mapping system following creation of a visualization matrix of the target chamber using a catheter with a magnetic sensor. In addition, the visualization of CWMS has been shown to be sufficiently safe for catheter manipulation. Therefore, the described method is important to reduce radiation exposure for CWMS users.

4.3 | Procedural duration and radiation exposure time during CS catheter placement performed under fluoroscopic guidance and without fluoroscopy

In a meta-analysis, catheter ablation without fluoroscopy was associated with decreased radiation exposure without increasing procedure time compared to catheter ablation under fluoroscopic guidance.⁹ These findings were consistent with those from our study. Of note, there was no increase in procedural time despite creation of visualization matrix for the CS, right atrium, and SVC using an irrigation catheter. This reflects the short median time needed for CS catheter placement (234 s) and the advantage of creating a FAM of the SVC before attempting SVC isolation.

4.4 | Effect of reducing radiation exposure for medical staff and patients during catheter ablation

With respect to the medical staff's radiation exposure, reducing fluoroscopy during catheter ablation may decrease the risks associated with radiation exposure. However, although CS cannulation of CWMS without fluoroscopy decreased radiation exposure, radiation exposure during preoperative CT was higher compared to that during catheter ablation. Therefore, preoperative MRI might be better than preoperative CT in terms of reducing radiation exposure for the patients. Along these lines, for one of the patients included in the present study, MRI was performed as preoperative evaluation because CT was performed several times for evaluation of other diseases during the 5 months before catheter ablation.

4.5 | An optional method for CS catheter placement

cases. In fact, CS catheter placement was challenging in one case in the present study owing to anatomical position of the CS had changed following a previous cardiac surgery. Although the CS catheter placement without fluoroscopic guidance was uneventful, CS catheter placement under fluoroscopic guidance required amount of time. Therefore, the proposed method may be an option for cases of CS catheter placement that are challenging under fluoroscopic guidance.

4.6 | Study limitations

A few limitations of our study needed to be acknowledged. First, of the 47 patients in the group without fluoroscopic guidance group, 30 patients underwent catheter ablation without fluoroscopy throughout the procedure. In these patients, reduction in the time of radiation exposure was intended not only during CS catheter placement but also during access to vein puncture, sheath advancement, transseptal puncture, and catheter manipulation in the left atrium. Of note, fluoroscopic guidance is not needed following transseptal puncture in all patients; therefore, radiation exposure after this time point would not be different between the two groups.

Second, the number of patients with confirmed CS cannulation time in the group with fluoroscopic guidance was only 22, owing to the retrospective nature of this study. A significant difference may therefore had been noted, if the CS cannulation time had been recorded for all patients in the group with fluoroscopic guidance.

Third, visualization of other CWMS catheters (i.e., CS catheter [EP star; Japan Lifeline], duo-decapolar catheter [Inquiry, Abbott], and cryoablation catheter [Freezor Xtra; Medtronic]) were confirmed by using the method presented in this study, this fact was not tested during the present study.

Fourth, CS cannulation was not attempted via femoral vein without fluoroscopy. It has been shown that CS catheter cannulation via femoral vein is more difficult compared to subclavian or jugular vein approach.¹¹ In addition, CS morphology has been reported changed in some cases, owing to the prior cardiac surgery.¹² Therefore, the proportion of success of the method presented in this study via femoral vein may vary, especially for the patients who have undergone prior cardiac surgery.

5 | CONCLUSIONS

Catheter placement into the CS without fluoroscopic guidance is safe, feasible, and can be achieved without interruption in the ablation procedure even when using a CWMS. This method can generally be used to reduce radiation exposure. And, it might be one of the options for CS catheter insertion in cases wherein the cardiac anatomy was altered due to a previous cardiac surgery.

AUTHOR CONTRIBUTIONS

It has been shown that there are wide variations in CS anatomy,¹⁰ and this may increase the difficulty of CS catheter placement in some

Conceptualization: Tadashi Hoshiyama. Data curation: Tadashi Hoshiyama, Satoshi Sumi, Shozo Kaneko. Formal Analysis: Tadashi

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Hoshiyama. Investigation: Tadashi Hoshiyama. Methodology: Tadashi Hoshiyama. Supervision: Hitoshi Sumi, Shozo Kaneko, Yusei Kawahara, Miwa Ito, Hisanori Kanazawa, Seiji Takashio, Eiichiro Yamamoto, Kenichi Matsushita, Kenichi Tsujita. Writingoriginal draft: Tadashi Hoshiyama. Writing-review & editing: Tadashi Hoshiyama, Hitoshi Sumi, Shozo Kaneko, Yusei Kawahara, Miwa Ito, Hisanori Kanazawa, Seiji Takashio, Eiichiro Yamamoto, Kenichi Matsushita, Kenichi Tsujita.

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CONFLICT OF INTEREST

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DATA AVAILABILITY STATEMENT

The data related to this study are not available due to privacy or ethical restrictions.

ETHICS APPROVAL AND INFORMED CONSENT

The study protocol was approved by the Human Research Committee of Kumamoto University Hospital (approval number, Rinri 2329). An opt-out method was used for the consent.

ORCID

Tadashi Hoshiyama 🕩 https://orcid.org/0000-0002-1315-5904

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