Magnetic Navigation System and CT Roadmap-Assisted Percutaneous Coronary Intervention: A Comparison to the Conventional Approach

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ABSTRACT: Background. Computed tomography coronary angiography (CTCA) has been successfully integrated with the magnetic navigation system (MNS) to facilitate a roadmap-assisted percutaneous coronary intervention (PCI). The aim of this study was to compare this new approach of PCI versus conventional PCI regarding the difference of contrast usage, x-ray exposure, procedure success, and in-hospital expenses. **Methods.** Thirty-eight patients with stable coronary artery disease and coronary artery lesions of ≥70% diameter stenosis diagnosed by both pre-procedure CTCA and coronary angiography (CAG) were enrolled to receive the MNS and CT roadmap-assisted PCI. Another 38 patients were consecutively recruited to receive conventional PCI, matched with the MNS group by the vessel and lesion type base on American College of Cardiology/American Heart Association criteria. **Results.** Regarding the process of the guidewire placement, wherein the technical difference of the two procedures exists, the median contrast usage for guidewire crossing was significantly lower in the MNS group than in the conventional group [0.0 mL (interquartile range [IQR], 0.0-3.0 mL) vs 5.0 mL (IQR, 3.1-6.8 mL); $P<.001$], with zero contrast usage in 25 of the 44 guidewire placements in the MNS group, but in none of the conventional group; the radiation dosage for guidewire crossing in the MNS group was also significantly lower than in the conventional group (235.8 μGym^2 [IQR, 134.9-455.1 μGym^2] vs 364.4 μGym^2 [IQR, 223.4-547.2 μGym^2]; $P=.033$). There were no significant differences between the two groups concerning the total contrast usage, total radiation dosage of the PCI, the procedural fees, or the overall in-hospital expenses. All of the enrolled vessels were successfully intervened in both groups. **Conclusion.** In PCI of simple lesions, the application of CT guidance and magnetic navigation had modest impacts on radiation dosage and contrast usage for wire crossing, but no impact on overall radiation dosage or contrast usage for the procedure. In addition, the use of CT roadmap and MNS was likely more expensive compared to PCI using conventional radiographic technique.

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Magnetic navigation system (MNS)-assisted percutaneous coronary interventions (PCI) have been applied in clinical practice for several years. The major technical innovation of this novel procedure exists in the process of the guidewire placement, while the majority of the procedure (balloon dilation, stenting, and postdilation as needed) is the same as conventional PCI.[1-5] Recently published studies have shown that MNS-assisted PCI may improve success rate in certain complex cases and reduce contrast usage and radiation exposure, which depends upon different navigation modes and image integration strategies.[6-13] More recently, Li et al[14] have successfully extracted vessels from computed tomography (CT) images and transferred them to the live fluoroscopic screen after reconstruction, which then functioned as roadmaps to guide the MNS-assisted PCI; however, the advantages of this new PCI approach have not been fully investigated. This study aimed to compare MNS and CT roadmap-assisted PCI with conventional PCI regarding contrast usage, radiation exposure, procedural success rate, and in-hospital expenses.

Methods

Study population. This study was carried out in a single center in a period from January 2011 to July 2011. Thirty-eight patients with stable coronary disease and coronary artery lesions of ≥70% diameter stenosis diagnosed by both preprocedure CT coronary angiography (CTCA) and percutaneous coronary angiography were recruited to compose the MNS group before initiating the coronary intervention. Patients in the MNS group received MNS and CT roadmap-assisted PCI. The decision for a preprocedure CT scan was at the attending physician's discretion. Patients who met the following criteria were excluded: (1) acute coronary syndromes; (2) angiographic total occlusion; (3) not eligible for PCI due to severe or diffuse lesions requiring CABG; and (4) contraindication magnet exposure (eg, patients with pacemakers, metal valves, and prosthetic metal hip or knee). The study conformed to institutional guidelines and those of the American Physiological Society. Written informed consent was obtained from each patient.

Another 38 patients who did not receive preprocedure CTCA examination were consecutively recruited to compose the control group on condition that their coronary artery lesions matched with the MNS group by the vessel and lesion type based on American College of Cardiology/American Heart Association (ACC/AHA) criteria. Patients in the control group received conventional PCI.

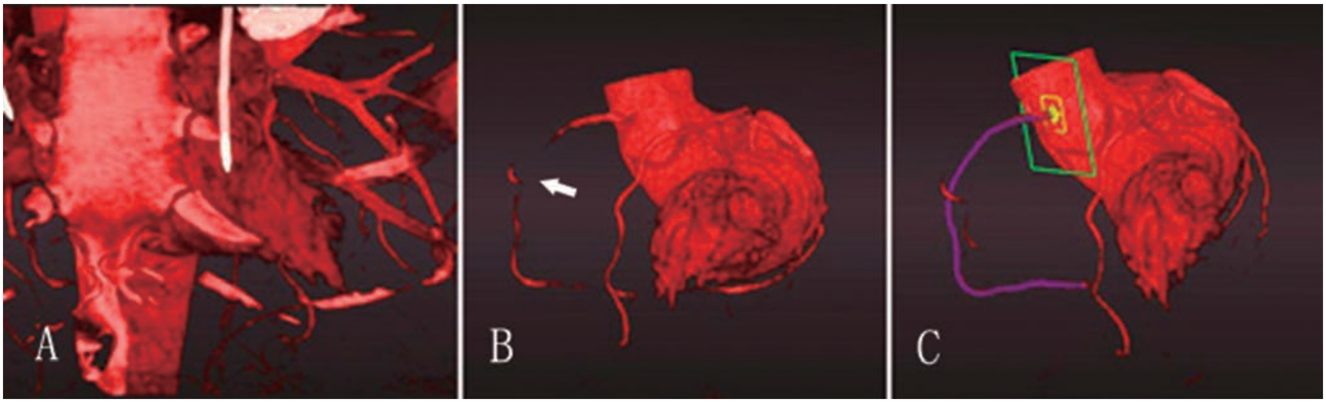

Figure 1. *Reconstruction of the coronary arteries from computed tomography coronary angiography.* **(A)** *Preliminary image.* **(B)** *Coronary arteries exposed by manual editing of the computed tomography image; arrow shows a severe stenosis in the mid-right coronary artery.* **(C)** *Reconstruction of the right coronary artery.*

MNS and CT roadmap-assisted PCI. MNS-assisted PCI has been described in detail elsewhere.[14] Briefly, MNS (Niobe II; Stereotaxis) is composed of two large permanent magnets that can be positioned in parallel at the two sides of the operating table during magnetic intervention. They generate a uniform magnetic field of 0.08 T with a diameter of about 6 inches in the center of the patient's thorax. An MNS-compatible guidewire (Titan; Stereotaxis), which includes a tiny magnet embedded in the tip, is maneuvered by modulating the orientation of the magnetic field, which changes the direction of the guidewire tip. The change of the magnetic field orientation can be achieved by clicking and dragging the vector in the touch screen using the Navigant Workstation (Stereotaxis) located at the table side. The operator thus can manually advance the magnetic guidewire and change the direction of the wire tip *in vivo* while referring to the roadmap extracted from CT images. Contrast flush is performed to check the wire position according to the operator's discretion. After the magnetic guidewire is in position, the rest of the procedure is the same as the conventional PCI. The operators in the MNS arm were also using conventional x-ray imaging to evaluate stent positioning, stent deployment and sizing, and final results of stent deployment. The wire is finally pulled out after the stent is deployed, and the two magnets are stowed upon completion of the procedure.

Incorporating CT images into the Navigant software and creating roadmaps have been described in a previous study.[14] In brief, CT images were imported into the Navigant workstation (Figure 1A), after which the main branches of the coronary arteries were extracted and reconstructed (Figures 1B and 1C). Meanwhile, two diagnostic cines of the target vessel at least 30° apart were chosen and transferred into Navigant. The datasets were aligned by landmark registration, whereby an intrinsic fiducial vessel marker was selected on two diagnostic cines of the target vessel, after which the same landmark was identified and selected from the CT image, and then the software automatically aligned the x-ray and CT images by aligning the selected landmarks. Manual alignment was allowed if necessary. Finally, the reconstructed CT vessel was transferred onto the live fluoroscopic screen as a roadmap, and the magnetic vector could be changed on the touch screen at the table side referring the route of the roadmap (Figure 2).

The technical parameters for a CT scan were as follows:[15] imaging acquisition was performed using a 64-slice dual-source CT scanner (Somatom Definition; Siemens Healthcare). CTCA requires a bolus injection of 80-100 mL of contrast (Ultravist 370; Schering) in the antecubital vein at a velocity of 5 mL/s, followed by flushing with 40 mL of saline. Scanning was automatically triggered by the bolus tracking technique included in the scanner. The scan was performed with the following parameters: rotation time, 330 ms; tube voltage, 120 kV; effective tube current, 380-420 mAs; pitch, 0.2-0.43 (depending on the heart rate); collimation width, 64 × 0.6 mm; slice width, 0.75 mm; reconstruction increment, 0.5 mm; and reconstruction kernel, B26f. An electrocardiogram was recorded during data acquisition, and electrocardiographic pulsing was applied to reduce radiation exposure. Images of the best diastolic phase and the best systolic phase were automatically reconstructed by using the retrospective electrocardiogram gate and the optimal cardiac phase that displayed the minimal motion artifacts, which was individually determined for the cases with arrhythmia.[16,17] It is important to note that patients recruited into the MNS group were exposed to additional radiation and as much as 80-100 mL contrast media in the process of the CT scan; however, the preprocedure CT scans in this study were performed prior to admission at the attending physician's discretion, while not mandated by the study investigators.

Procedural definitions. Vessel lesion classifications were based on ACC/AHA criteria. Lesion length and stenosis percentage were determined with the quantitative coronary angiography (QCA) software (Artis; Siemens Healthcare). *Procedure success* was defined as successful stent implantation without major complications. Contrast usage and x-ray exposure dosage during the guidewire placement were recorded for each case during the period when the guidewire exited from the guiding catheter until it reached its final position, far distal to the lesions. *Procedure time* was defined as the time from guidewire exiting from the guiding catheter to completion of stent deployment. Total x-ray exposure dosage, total contrast usage in the procedure time, as well as procedural fees and total in-hospital expenses (including the costs of the CT scan and the Stereotaxis guidewire) of the patients were all recorded.

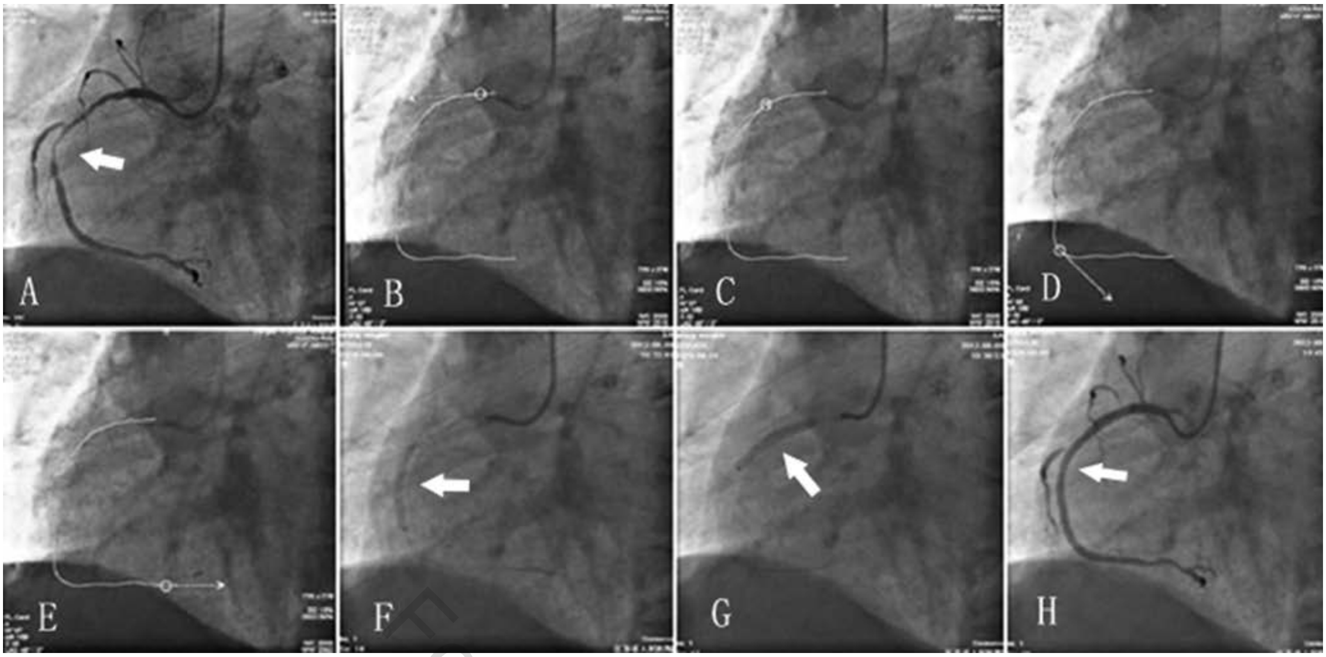

Figure 2. *Magnetic navigation system and computed tomography (CT) roadmap-assisted percutaneous coronary intervention.* **(A)** *Right coronary angiography, arrow shows a severe stenosis in the mid-right coronary artery (RCA).* **(B)** *CT-derived roadmap (white line) projected on the x-ray screen, arrow shows the direction of the magnetic field.* **(C, D, E)** *CT-derived roadmaps (white line) projected on the x-ray screen, arrows show the changes of the direction of the magnetic field while advancing the guidewire.* **(F, G)** *Fluoro image, arrow shows the successfully deployed stents.* **(H)** *Right coronary angiography, arrow shows that the stenosis of the RCA disappeared after stent deployment.*

Statistical analysis. Continuous data were expressed as mean ± standard deviation or median (25%-75% interquartile range [IQR]) where appropriate, and were compared using the two-sided student t-test or Mann-Whitney U-test. Categorical data were expressed as number and percentage, and were analyzed with the Pearson χ^2 test. A 2-sided *P*-value of <.05 was considered statistically significant. Stata 9.2 (StataCorp) statistical software was used for data analysis.

Results

Baseline characteristics. Both the MNS and the conventional groups included 38 patients, with 44 target vessels in each group. There were no differences in the baseline characteristics between the two groups (Table 1).

Procedure results. The CT vessel reconstruction and registration process for the three major coronary arteries averaged 8.2 minutes (IQR, 5.9-11.5 minutes). All target lesions were successfully crossed by the guidewires and all target vessels were successfully treated in both the MNS and control groups. Balloons per vessel, stents per vessel, and procedure time were not significantly different between the two groups (Table 2).

The contrast usage for guidewire crossing was significantly lower in the MNS group than in the conventional group (0.0 mL [IQR, 0.0-3.0 mL] vs 5.0 mL [3.1-6.8 mL]; *P*<.001). The contrast usage was zero in 25 of the 44 guidewire placements in the MNS group, but in none of the conventional group. The radiation exposure for guidewire crossing in the MNS group was significantly lower than in the conventional group (235.8 μGym^2 [IQR, 134.9-455.1 μGym^2] vs 364.4 μGym^2 [IQR, 223.4-547.2 μGym^2]; *P*=0.033; Table 2). However, there were no significant differences between the MNS group and the conventional group concerning the total contrast usage, total radiation exposure for PCI, procedural fees, or total hospital expenses (Table 2). No major complications occurred in either group during the procedure.

Discussion

This study showed that MNS and CT roadmap-assisted PCI significantly reduced contrast usage for guidewire crossing compared with the conventional approach, with zero contrast usage in 57% of the guidewire placements in the MNS group. In addition, this new PCI approach significantly reduced radiation exposure for the guidewire placement compared with conventional PCI.

MNS and CT roadmap-assisted PCI has been rarely investigated. Ramcharitar et al[11] first reported their study of integrating multi-slice CT coronary angiography with MNS in 15 patients, where contrast agents were used in 4 out of 15 recruited patients (26.7%). More recently, Li et al[18] successfully integrated dual-source CT coronary angiography with MNS, and facilitated a MNS and CT roadmap-assisted PCI. To the best of our knowledge, this is the first study comparing MNS and CT roadmap-assisted PCI with conventional PCI regarding the difference of contrast usage, x-ray exposure, procedure success, and expenses.

It was reported that MNS-assisted PCI resulted in a similar procedural success rate, operation time, and contrast usage, with a trend toward shorter guidewire crossing time and less x-ray exposure when compared to conventional PCI.[19] In this study, we added the CT roadmap to the magnetic navigation.

Table 1. Baseline characteristics of MNS and conventional groups.

	MNS Group	Conventional Group	*P*-Value
Patients (n)	38	38	
Male	29 (76.3%)	31 (81.6%)	.317
Ages (years)	62.5 ± 10.2	64.6 ± 10.7	.382
Hypertension	24 (63.2%)	22 (57.9%)	.220
Diabetes	8 (21.1%)	9 (23.7%)	.076
Vessels (n)	44	44	
LAD	26 (59.1%)	26 (59.1%)	1.000
Diagonal	1 (2.3%)	1 (2.3%)	
LCX	7 (15.9%)	7 (15.9%)	
RCA	10 (22.7%)	10 (22.7%)	
Lesion type			1.000
A	14 (31.8%)	14 (31.8%)	
B1	17 (38.6%)	17 (38.6%)	
B2	11 (25.0%)	11 (25.0%)	
C	2 (4.5%)	2 (4.5%)	
Lesion length (mm)	23.4 ± 10.6	20.9 ± 9.1	.234
Stenosis (%)	81.2 ± 9.8	84.0 ± 7.4	.137

MNS = magnetic navigation system; LAD = left anterior descending artery; LCX = left circumflex; RCA = right coronary artery.

This functioned especially well in keeping the correct curve of the vessels, which is of key importance while applying the magnetic vector to ensure the appropriate direction for advancing the guidewire.[18] A vessel roadmap overlaid on the live x-ray screen would enable the operator to rely less on contrast and fluoroscopy to detect the vessel, which might explain the significant reduction in the contrast usage and radiation exposure during the guidewire placement, wherein the technical difference between the CT/MNS-assisted PCI and conventional PCI exists. It should be noted that the guidewire placement was a subset of the whole PCI procedure, so the differences in the contrast usage and radiation exposure between the two groups were diluted to nonsignificant while comparing the total contrast usage and total radiation exposure for PCI. However, due to a low-risk cohort, with few class B2/C lesions, the benefits of this novel approach of PCI in real-world settings may not be seen.

There are concerns that the patients recruited into the MNS arm were exposed to additional radiation and as much as 80-100 mL of contrast media in the process of the CT scan. Thus, it is not recommended to perform a CT roadmap-assisted PCI for all patients. In real-world settings, a CT roadmap-assisted PCI would be indicated in the following conditions: (1) patients who have received CTCA before admission; or perhaps (2) patients who need to receive a CTCA before PCI due to clinical requirements (eg, patients who are diagnosed with an old myocardial infarction and probable chronic total occlusion or patients who have a history of a variant origin of the coronary artery).

The procedural fees and total in-hospital expenses were nonsignificantly higher in the MNS group than in the conventional group. However, the magnetic guidewires were "charged" as the regular wires in this study since the market price of the magnetic guidewire has not been defined; the expenses in the MNS group would be higher if the magnetic guidewires were more expensive in a "real-world" setting.

A roadmap image could also be created from the coronary artery angiography (CAG). However, if a coronary artery was totally occluded, the roadmap could not be precisely created from the CAG since the distal part of the occluded vessel would not present in the CAG. By contrast, CTCA can disclose the distal part of the occluded vessel due to the presence of the coronary collaterals and the non-select characteristics of CTCA.[18] A previous study has proven that CT roadmap-assisted PCI for total occlusions is feasible.[18] We believe that the major advantage of MNS and CT roadmap-assisted PCI

Table 2. Procedure results of MNS and conventional groups.

	MNS Group (n = 44)	Conventional Group (n = 44)	*P*-Value
Guidewire crossing	44 (100%)	44 (100%)	1.000
Radiation for wire crossing (μGym^2)	235.8 (134.9-455.1)	364.4 (223.4-547.2)	.033
Radiation for PCI (μGym^2)	6901.5 (4337.0-9892.0)	7028.5 (4810.5-10997.5)	.234
Contrast for wire crossing (mL)	0.0 (0.0-3.0)	5.0 (3.1-6.8)	.000
Contrast for PCI (mL)	85.0 (50.0-108.0)	87.5 (64.0-125.0)	.115
Balloons per vessel (n)	1.2 ± 0.4	1.1 ± 0.3	.063
Stents per vessel (n)	1.3 ± 0.6	1.2 ± 0.5	.415
Procedure success	44 (100%)	44 (100%)	1.000
Procedure time (minutes)	17.0 (12.2-20.0)	20.0 (14.0-25.8)	.146
Total hospital expenses (US dollars)	9953.6 ± 4092.1	9708.5 ± 2866.9	.763
Procedural fees (US dollars)	7821.9 ± 3380.4	7694.3 ± 2511.5	.852

Data given as n (percentage), median (interquartile range), or mean ± standard deviation; MNS = magnetic navigation system; PCI = percutaneous coronary intervention.

may lie in total occlusion interventions, which warrants further investigation. To avoid the heterogeneity of the lesion characteristics, we did not include total occlusions in this study.

The CT vessel reconstruction and registration process for the three major coronary arteries averaged 8.2 minutes to obtain; however, it would not necessarily prolong the whole procedure time since it was performed by an experienced technician while the operator was performing all other aspects of the procedure.

Study limitations. Our study has potential limitations. First, it is not a randomized research study. Randomly distributing the patients to CT scan would deviate from the principle of ethics; therefore, a paired study was planned, and the patients were matched in vessel and lesion type based on ACC/AHA criteria. Second, vessel registration fidelity is primarily assessed by the user based on their visual examination of the vessel overlays in each x-ray view. Caution must be taken to select the two x-ray views at the same cardiac and respiration cycles. However, the purpose of the image registration is primarily to provide a vector roadmap to reduce the operator's reliance on the real-time arteriography while facilitating navigation. Third, total occlusions were excluded and only 4.5% type-C lesions were recruited in this study. Further studies are required to investigate the advantages of MNS and CT roadmap-assisted PCI in more complex lesions, especially in total occlusions.

Conclusions

In PCI of simple lesions, the application of CT guidance and magnetic navigation had modest impacts on radiation dosage and contrast usage for wire crossing, but no impact on overall radiation dosage or contrast usage for the procedure. In addition, the use of CT roadmap and MNS was likely more expensive compared to PCI using conventional radiographic technique.

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