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Original Article

Peripheral Interventions Radiation Exposure Reduction Using a Sensor-Based Navigation System: A Proof-of-Concept Study

Philippe L. L'Allier, MD,[a] Louis-Philippe Richer, PhD,[b] Luke C. McSpadden, PhD,[b] and Jean-François Dorval, MD[a]

[a] *Department of Medicine (Interventional Cardiology), Montreal Heart Institute (Université de Montréal), Montreal, Quebec, Canada*

[b] *Abbott, Sylmar, California, USA*

ABSTRACT

Background: Intravascular catheter positioning is done with radiography imaging. Increasing evidence indicates excessive ionizing radiation exposure for patients and physicians during catheterization procedures, making solutions to reduce radiation exposure a priority. This study evaluated the feasibility and impact of using sensor-based magnetic navigation on (i) fluoroscopy time and (ii) positioning accuracy and safety of a peripheral angioplasty balloon catheter.

Methods: All patients ($n = 10$) underwent a balloon-positioning protocol using 2 navigation methods sequentially: (i) magnetic navigation with minimal fluoroscopy; (ii) fluoroscopic navigation. The navigation method order was randomized, and 4 consecutive placements per method were performed. A target vascular bifurcation was used as a fiduciary landmark for both methods to determine accuracy.

Results: Balloon placements were successful with both navigation methods in all subjects, and no adverse events occurred. Magnetic guidance led to significant reductions in fluoroscopy time (0.37 ± 1.5

RÉSUMÉ

Contexte : Le positionnement d'un cathéter intravasculaire fait appel à l'imagerie radiographique. De plus en plus de données probantes indiquent que les patients et les médecins subissent une surexposition aux rayonnements ionisants pendant le cathétérisme, ce qui fait des solutions de réduction de l'irradiation une priorité. Cette étude a permis d'évaluer la faisabilité du guidage magnétique par capteur et son effet sur (i) la durée de la fluoroscopie et (ii) la précision et la sécurité du positionnement d'un cathéter d'angioplastie périphérique à ballonnet.

Méthodologie : Chez tous les patients ($n = 10$), le positionnement du ballonnet a été effectué en fonction d'un protocole fondé sur deux méthodes de guidage mises en œuvre séquentiellement : (i) guidage magnétique avec fluoroscopie minimale; (ii) guidage fluoroscopique. L'ordre dans lequel les méthodes de guidage ont été mises en œuvre a été randomisé, et quatre positionnements consécutifs par méthode ont été effectués. Une bifurcation vasculaire cible a servi de repère de

Conventional endovascular procedures require catheter and wire navigation, using radiography-based fluoroscopy and cine angiography, to reach specific anatomic landmarks and perform diagnostic and therapeutic interventions. This conventional tool navigation method may lead to significant ionizing radiation exposure for physicians, laboratory staff, and patients. In addition, minimizing the use of iodine-based contrast media, required for vessel visualization, has significant clinical benefit in many patients. Recent studies have demonstrated the direct and derived impacts of medical radiation exposure.[1-4] Higher risks of left-brain cancer and/or eye-lens opacities are among the most serious direct impacts for interventional physicians, and serious neck and back problems due to wearing lead aprons are among the secondary issues. Concomitantly, the safety and feasibility of using robotic systems to reduce medical radiation exposure have been reported.[5,6] These publications showed that robotic navigation reduced medical radiation exposure, but learning curves and costs, among other factors, have limited the adoption of this technology. Magnetic navigation (MgN) technologies may have a role in interventional procedural guidance to substantially reduce ionizing radiation (IR) exposure of the patient and operator during peripheral interventions. We assessed the safety, feasibility, and impact on reducing IR exposure during peripheral arterial navigation of using a sensor-based electromagnetic tracking system.

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Ethics Statement: The protocol was approved by the institutional research and ethics committees.

Corresponding author: Dr Jean-François Dorval, Department of Medicine, Montreal Heart Institute, 5000 Bélanger, Montréal, Quebec H1T 1C8, Canada. Tel.: +1-514-376-3330 x3010; fax: +1-514-593-2567.

E-mail: jf.dorval@umontreal.ca

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vs 15.0 ± 8.1 seconds, $P < 0.001$) and dose (0.3 ± 1.2 vs 24.1 ± 23.8 μGy.m^2, $P < 0.01$). The time duration for balloon alignment was similar for the 2 navigation methods (4.8 ± 1.4 vs 4.8 ± 2.3 seconds, $P = 0.89$), and the accuracy was almost identical (0.51 ± 0.41 vs 0.51 ± 0.32 mm, $P = 0.97$).

Conclusions: These results demonstrate the feasibility of using sensor-based magnetic guidance during simple peripheral interventional procedures; a significant reduction in ionizing radiation was achieved, with excellent positioning accuracy and safety. The clinical applications of magnetic guidance for device navigation during more complex percutaneous procedures should be evaluated.

fond de chambre afin de déterminer la précision des deux méthodes.

Résultats : Les deux méthodes de guidage ont permis un positionnement adéquat du ballonnet chez tous les patients, et aucun événement indésirable n'est survenu. Le guidage magnétique a entraîné des réductions significatives de la durée de la fluoroscopie (0,37 ± 1,5 *vs* 15,0 ± 8,1 secondes, $p < 0{,}001$) et de la dose de rayonnement (0,3 ± 1,2 *vs* 24,1 ± 23,8 μGy.m^2, $p < 0{,}01$). La durée de l'alignement du ballonnet était similaire lors de la mise en œuvre des deux méthodes de guidage (4,8 ± 1,4 *vs* 4,8 ± 2,3 secondes, $p = 0{,}89$), et la précision était presque identique (0,51 ± 0,41 *vs* 0,51 ± 0,32 mm, $p = 0{,}97$).

Conclusions : Ces résultats démontrent la faisabilité du guidage magnétique par capteur dans le cadre d'angioplasties périphériques simples. L'exposition aux rayonnements ionisants a été réduite de façon significative, et la précision ainsi que la sécurité du positionnement se sont avérées excellentes. Les applications cliniques du guidage magnétique dans le contexte d'interventions percutanées plus complexes représentent une avenue de recherche à explorer.

Methods

Study population

The study consisted of patients over 18 years of age, scheduled for a clinically indicated catheterization procedure using the femoral access at a single centre (n = 10). All patients provided written informed consent. Patients with thrombophilia, critical limb ischemia. an unstable clinical condition, or conditions limiting life expectancy were excluded, as were minors, pregnant women, and patients involved in any other on-site clinical investigation. The protocol was approved by the institutional research and ethics committees.

Protocol initial steps and anatomic landmark identification

This prospective single-centre acute study compared the following 2 angioplasty catheter navigation methods in each patient: (i) MgN (MediGuide, Abbott, St. Paul, MN) and (ii) standard fluoroscopy (Fluoro; Artis Zee, Siemens, Erlangen, Germany, the gold standard). Successful femoral vascular access was secured with a 7F introducer sheath, and an 0.035" wire was positioned in the descending aorta. For both methods, assessment of vascular anatomy and target fiduciary landmark identification (typically the iliac bifurcation) required the acquisition of 2 guidance cineloops (5 seconds each, > 40 degrees apart, typically right anterior oblique 20 and left anterior oblique 20) with contrast-media injections in vessels. The MgN system used in this study required the 2 guidance cineloops to display the roadmap and detectable tool positions on it. The radiation exposure and contrast use for these guidance acquisitions were not considered in the comparison of the 2 methods, as they were identical. Fluoroscopy and cine angiography were performed while respecting the standard ALARA (as low as reasonably achievable) principles, including keeping the fluoroscopy frame rate to 7.5 images per second, with identical settings used in both methods.

After cineloops completion, a 0.014" guidewire bearing a magnetic sensor at its distal tip (CPS Excel, Abbott, St. Paul, MN) was introduced in the vasculature and was navigated toward the target. Continuous wire-sensor position monitoring was possible, as turning the fluoroscopy system on automatically activated the MgN system. Thus, the 0.014" sensor-enabled guidewire intravascular navigation allowed capture of the 3-dimensional (3D) coordinates of the starting point, vessel 3D geometry, and target anatomic landmark. Alignment of the guidewire tip (home of the magnetic sensor) with the target (ie, iliac bifurcation) was confirmed with a short angiogram session and a small injection of contrast. The sensor-enabled guidewire was then introduced in the central lumen of a peripheral percutaneous transluminal angioplasty (PTA) balloon catheter (PowerFlex Pro; Cordis, Santa Clara, CA). The guidewire distal tip was aligned with the balloon catheter's distal radiopaque marker (Fig. 1A) and locked into position.

Intravascular navigation methods and systems

The navigation method sequence (Fluoro or MgN) was randomized, and each method was used to complete the same predefined balloon-positioning procedures. The Fluoro method used standard fluoroscopic and cine angiographic protocols; PTA balloon catheters with 2 central radiopaque markers were navigated under fluoroscopy. Small contrast injections were used to determine the location of the iliac bifurcation (the target anatomic landmark) and the balloon catheter's position relative to it, in 2 optimized orthogonal projections (typically the same ones used for the guidance cineloops).

A magnetic field generated in the patient body by an array of magnetic transmitters around the fluoroscopic detector allowed for sensor-enabled device detection. Device localization in the magnetic field required a patient reference magnetic sensor (PRS) at a fixed position. The magnetic reference then established a spatial link between the imaged area of the patient and the flat image detector. This link allowed for real-time display of the device sensor position over both orthogonal cineloops previously acquired (used as roadmaps), and compensation for respiratory movements. The simultaneous overlay of the PTA balloon position over 2 orthogonal

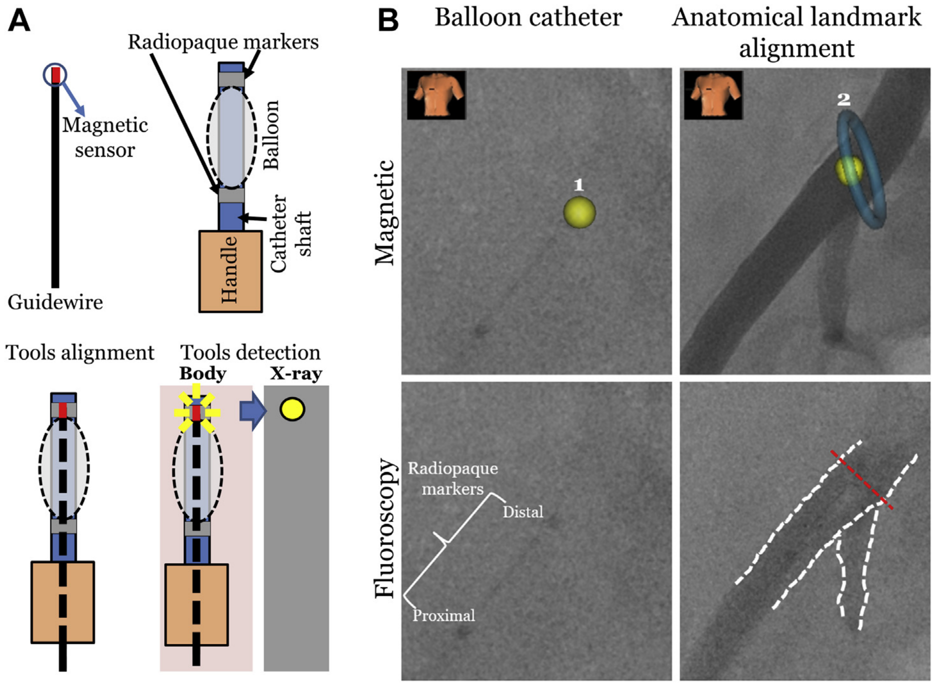

Figure 1. Balloon-catheter detection method. (**A**) Diagram depicting the method established for magnetic detection of the balloon-catheter position on pre-recorded angiogram cine-loops. (**B**) Example of the balloon-catheter representation for each navigation method (balloon-catheter column) and anatomic landmark targeted for alignment (1 = magnetic sensor location; 2 = Iliac bifurcation location).

roadmaps prevented the need for any subsequent angiography. In the MgN navigation protocol, the indirect localization of the radiopaque distal marker allowed angioplasty balloon alignment with the iliac bifurcation without use of fluoroscopy (Fig. 1B).

Balloon-positioning protocol

In each navigation of the prespecified sequence, the PTA balloon catheter was advanced from the femoral sheath to the target anatomic landmark (4 navigations/method, for a total of 8 placements per patient). The presence of the sensor-enabled guidewire at a fixed position in the PTA balloon catheter central lumen, for both navigation methods, allowed recording of its starting position, intravascular trajectory, and final alignment position in the magnetic navigation system. The operators were completely blinded to the MgN positional data when the fluoroscopic navigation method was used. To be saved in the system, correct placement of the balloon catheter had to be determined by consensus among the operators involved in the study. The magnetic navigation system also recorded fluoroscopy time for both methods for standardization purposes; and the radiograph system recorded the dose area product (DAP) for both methods.

The data acquired were retrospectively analyzed; characterization of positional accuracy of the PTA balloon catheter relied entirely on the data saved in the magnetic navigation system.

Endpoints

The primary endpoint was average fluoroscopy time in seconds required to navigate the balloon catheter to the target anatomic landmark. The secondary endpoints were the following: (i) placement accuracy (distance in millimeters between the balloon alignment marker and the bifurcation marker measured with the MgN system); (ii) total radiation exposure (DAP measured by the radiography system); (iii) total procedure time; (iv) average time duration for each balloon catheter—positioning attempt; (v) success of balloon navigation; and (vi) number of adverse events.

Data processing and statistics

The magnetic data were exported post-study from the MgN system. The time duration endpoints—time of radiation, time to complete the 4 alignments/navigation method, and time for each balloon positioning—were computed using the MgN system log. The difference between the DAP noted at the end vs beginning of each balloon alignment provided the radiation risk value for each alignment. The distances between the balloon alignment markers and the bifurcation marker were computed from the MgN positional 3D coordinate, using the Euclidian distance calculation method, for both navigation systems, a mathematical method to compute the length of a straight line between 2 points. The computation was done using Matlab software (Release 2019a; Matlab, Mathworks, Natick, MA).

Baseline characteristics are presented as counts and percentages for categorical variables, and as mean ± standard deviation for continuous variables (Excel 365. version 16.0, Microsoft, Redmond, WA). The primary efficacy analysis was conducted using positively adjudicated data according to the intention-to-treat principle (ITT population). Given that both catheter navigation methods were used in each subject, the fluoroscopy time (seconds) required for angioplasty catheter

Table 1. Patient baseline characteristics

Parameters	
Number of subjects	10 (9 males)
Mean age, y	68
Mean blood pressure, mm Hg	142/69
Risk factors: hypertension, hypercholesterolemia	9
Coronary artery disease with myocardial ischemia	2
Coronary artery disease without myocardial ischemia	1
Cardiomyopathy—valvular disease	6
Cardiomyopathy—others	2
Prior cardiac intervention—PCI, CABG	3
Prior cardiac intervention—valve repair	0

Values are n, unless otherwise indicated.

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

navigation to the target anatomic landmark (primary endpoint) was compared between the 2 navigation techniques, using a paired Student *t* test. All analyses were 2-sided and were conducted at the 0.05 significance level. Secondary endpoints assessed under the 2 navigation techniques and expressed as continuous variables were analyzed as the primary endpoint.

Results

Patient characteristics and navigation success

Ten patients were included in this study (Table 1). The iliac bifurcation was identifiable and was a usable anatomic reference in all patients. The guidewire and patient magnetic reference were adequately detected in all subjects. All alignments using both methods were deemed successful by the operators. No adverse events related to the experimental protocol were noted, including vessel dissections. No significant motion delay was observed by the operators during catheter positioning when using magnetic guidance.

Primary endpoint

The mean fluoroscopy time required to complete balloon-catheter alignment with the iliac bifurcation was significantly shorter with the MgN method, compared with the Fluoro navigation method (Fluoro: 15.0 ± 8.1 vs MgN: 0.37 ± 1.5 seconds, $P < 0.001$; Fig. 2). Of the 40 balloon alignments completed with the MgN method, fluoroscopy was needed in 3 of the alignments (7.5%). The fluoroscopy time ranged between 1.6 and 8.7 seconds and was used to confirm catheter trajectory (subjects 3 and 4), and to confirm final balloon alignment, which was needed due to inappropriate motion compensation by the MgN system in one patient. The average fluoroscopy radiation exposure was 24.1 ± 23.8 $\mu Gy.m^2$ with the Fluoro navigation method, and 0.3 ± 1.2 $\mu Gy.m^2$ for the MgN method ($P < 0.01$; Fig. 2), a 98.8% relative reduction. In the MgN method, focusing on radiation occurrences, minimal and maximal fluoroscopy radiation exposure were respectively 1.2 and 6.8 $\mu Gy.m^2$.

Secondary endpoints

Navigation accuracy. No significant difference was found in the alignment accuracy between the 2 navigation methods (Fluoro: 0.51 ± 0.32 mm vs MgN: 0.51 ± 0.41 mm, $P = 0.97$; Fig. 3A). The time required to align the catheter with the iliac bifurcation was similar for the 2 navigation methods (Fluoro: 4.8 ± 2.3 seconds vs MgN: 4.8 ± 1.4 seconds, $P = 0.89$). Inappropriate motion compensation made the MgN method more challenging in subject 8 but did not affect the accuracy of the alignment (Fluoro: 0.22 ± 0.06 mm vs MgN: 0.20 ± 0.04 mm to iliac bifurcation) or time to complete each navigation protocol (Fluoro: 137.2 seconds vs MgN: 155 seconds; Fig. 3B).

Time duration for protocol completion. The averaged time duration for completion of the 4 balloon-catheter alignments was 182.6 ± 65.8 seconds for Fluoro navigation vs 157.6 ± 72.0 seconds for the MgN method ($P = 0.28$). Dataset slopes from both navigation methods (Fig. 4A) indicate that operators decreased their protocol completion time by 13.7 seconds and 14.2 seconds, respectively, with every new subject enrolled in the study (Fig. 4B, for a specific case). Moreover, despite randomization, the MgN portion of the alignment protocol was completed sooner in 7 of 10 subjects. Regardless

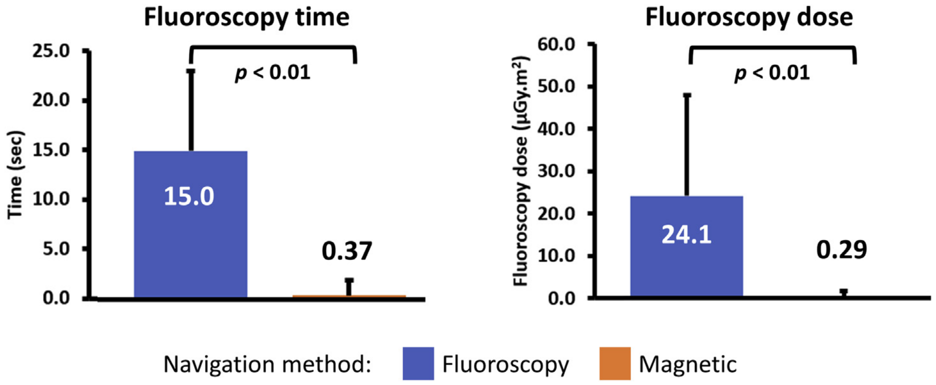

Figure 2. Radiation exposure per navigation method. Bar graphs show a significant difference between the navigation methods in both the fluoroscopy time and dose.

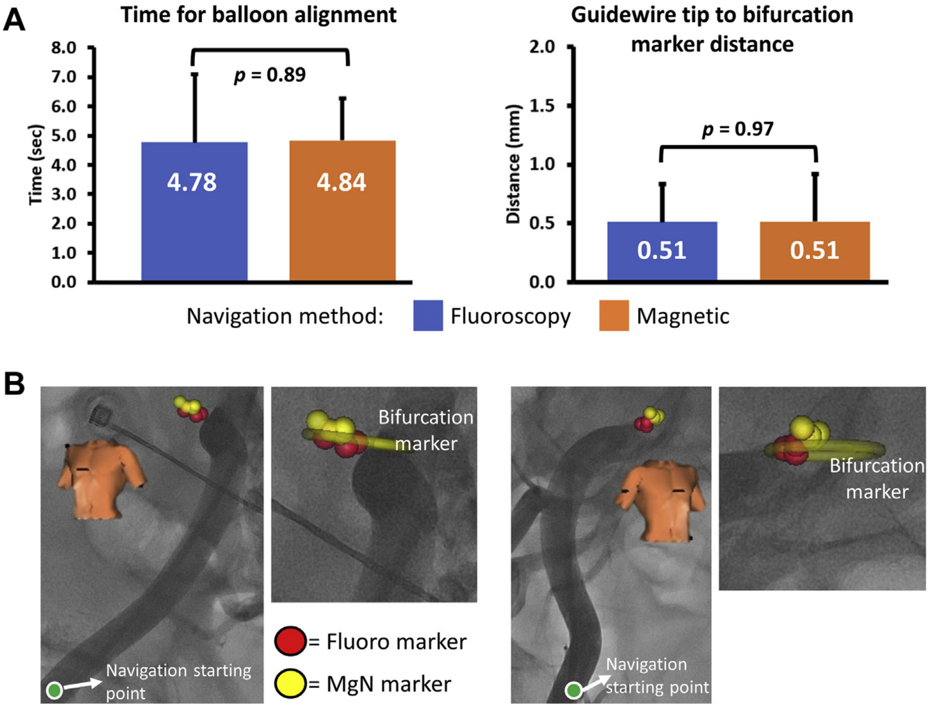

Figure 3. Alignment accuracy for each navigation method. (**A**) The fluoroscopy and magnetic methods required a similar amount of time for balloon alignment and had similar alignment accuracy between the guidewire tip and bifurcation. (**B**) Navigation markers location offset compared to iliac bifurcation. Fluoro, standard fluoroscopy; MgN, magnetic navigation.

of the technology, the navigation method randomized to be used first appeared to last longer but not significantly so (average time for the method randomized to be used first was 196.9 ± 79 seconds vs 139.0 ± 41.5 seconds for the method randomized to be used second [$P = 0.08$]). No significant differences were found in the navigation method randomized to be first vs second in the first 5 subjects enrolled in the study, or in the last 5 subjects (Fig. 4C).

Discussion

This proof-of-concept study showed the impact of magnetic guidance, here with the MgN system, on angioplasty catheter navigation toward a prespecified anatomic landmark in the peripheral arterial vasculature. This approach resulted in a significant reduction in medical radiation exposure, compared with standard fluoroscopic guidance. In addition, the feasibility, safety, and accuracy of peripheral vasculature magnetic navigation were also demonstrated. No significant difference was found between the 2 navigation methods in the time needed for balloon-alignment completion.

Performance of fluoroscopy-oriented procedures puts interventional cardiologists among the physicians with the greatest exposure to ionizing radiation[1,3,7] Results found in this study, in combination with those of previous studies evaluating similar navigation technologies,[5,6] do support magnetic navigation as a reliable alternative to conventional fluoroscopy tool navigation. In this study, MgN tracking and navigation capability was evaluated for angioplasty catheters in the peripheral vasculature for the first time. This approach involved adapting the configuration of the tracking technology to the chosen anatomic target (ie, the iliac bifurcation), notably the optimization of the PRS positioning. No impact was observed on the system tracking capability, spatial or temporal, or the resolution, as reflected by the similarity between the 2 navigation methods in the deviations in distance from the balloon distal marker to the iliac bifurcation . Moreover, the distance deviations measured in the peripheral system were similar to previously assessed measure deviations in the coronary vasculature, the system primary-intended network.[8,9] The PRS abdominal location made the system more sensitive to patients' breathing motion. One of the challenges met during one particular case involving suboptimal PRS positioning and irregular breathing pattern led to inappropriate motion compensation by the MgN system. However, a revision of PRS fixation on the subject improved the guidewire sensor icon positioning on the screen, allowing the balloon alignment protocol to be completed with the MgN method (< 2 seconds of fluoroscopy to confirm the first MgN alignment). No adverse events linked to the experimental protocol were observed in the subjects.

The main objective of MgN is to focus on decreasing medical radiation exposure during tool navigation. In this study, we observed a 98.5% decrease of fluoroscopy time, and a 99% decrease of exposure to ionizing radiation with MgN, despite basic system adjustments to the peripheral arterial vasculature. With appropriate optimization, the MgN impact on tool navigation—associated medical radiation exposure in a complete peripheral arterial vasculature procedure could be similar to that observed for other cardiac device implantation procedures.[10,11] One of the MgN system's most impactful features is the simultaneous location of the sensor-enabled tools on 2 orthogonal cineloops, for improved understanding of the vessel anatomic geometry.[12] Using simultaneous

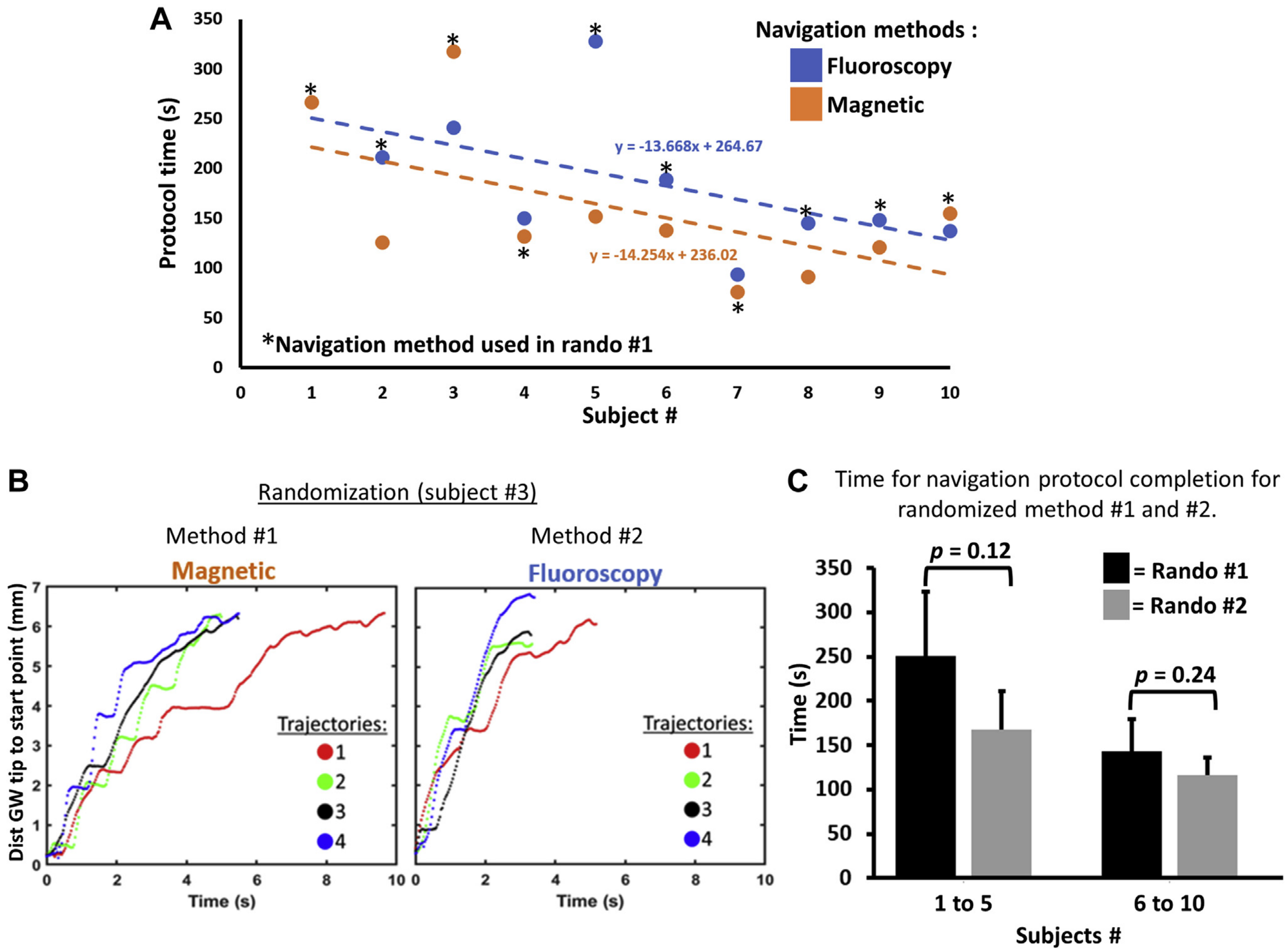

Figure 4. Learning curve and randomized navigation methods. (**A**) Time to complete each navigation protocol for each subject. (**B**) Example of balloon alignments (trajectories) in subject #3, with navigation method #1 (here magnetic navigation) the first balloon alignment (**red line** on Magnetic graph) took the longest time to complete (close to 10 seconds), as is seen in navigation method #2 (standard fluoroscopy). (**C**) Bar graph showing averaged time to complete randomized navigation protocols #1 and #2 for the first and last 5 subjects. Dist, distance; GW, guidewire; rando, randomized method.

orthogonal views is part of the standard procedures in electrophysiology.

In this study, the protocol completion time for each navigation method reflected the rapid learning curve experienced by the physicians. The vessel linear geometries may partly explain this learning pace, but they allowed the physicians to focus on the protocol instead of worrying about the vessel complexity. Thus, the learning curve provides a more accurate reflection of the physician's adaptation to the protocol and navigation technology. No statistical differences were found between randomized navigation method #1 versus #2, overall or when focusing on the first 5 vs the last 5 cases. However, the protocol completion time difference between randomized method #1 and #2, bigger in the first 5 cases compared to the last 5 cases, suggested an improved understanding of the navigation protocol and MgN system by the physicians. Despite the knowledge gain depicted by the decreased procedure time, the small sample size indicates we are still at the beginning of the learning curve. Publications on the MgN system in the cardiac venous network for cardiac resynchronization therapy implant did show a learning curve of 40 cases[10,13] to reach a consistent fluoroscopy exposure decrease. Given the higher diversity of the peripheral procedures (locations, site anatomy, etc.), a learning curve beyond 40 cases should probably be expected. For example, the identification of the optimal PRS location in each peripheral procedure could impact the learning curve.

Study limitations

This is a single-centre feasibility study with a small sample size. All balloon-catheter alignments were performed by an expert interventional cardiologist with experience in peripheral procedures. The absence of a predetermined, standardized location for the system magnetic reference (the PRS) affected the navigation system breathing-compensation algorithm. The indirect balloon-catheter magnetic localization methodology allowed us to perform this proof-of-concept study but limited its applications to simple vessel geometry. Finally, given that a navigation system was being evaluated, we focused the impact evaluation on the tool navigation portion of the procedure. Thus, the medical radiation exposure quantification was recorded only during catheter navigation for this proof-of-concept. For a given peripheral procedure, assuming that the optimal PRS location would be known, an exhaustive, skin-to-skin assessment of medical radiation exposure could provide refined data about the total radiation exposure involved.

Conclusions

This proof-of-concept study demonstrated the feasibility of MgN guidance for PTA balloon-catheter navigation in peripheral vessels with simple geometry. This approach resulted in a significant reduction in fluoroscopy time and medical radiation exposure. Furthermore, MgN provided adequate positioning accuracy and safety of balloon-catheter placement. Identification of the optimal location on the abdomen for the PRS, one of the main components for accurate MgN tracking, remains to be refined. The clinical applications of MgN for peripheral vascular procedures should be developed and studied further.

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Disclosures

Louis-Philippe Richer and Luke C. McSpadden are employees of Abbott. The other authors have no conflicts of interest to disclose.

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