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RESEARCH LETTER

Fully Teleoperated Peripheral Endovascular Interventions With a Novel Robotic System

A First in Human Study

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Endovascular robotic systems have emerged as a potential solution to reduce radiation exposure to medical personnel, enable teleoperation in areas lacking certain interventional expertise within a specific time frame, and possibly enhance procedural precision and stability.[1-4] Despite these advantages, the broader adoption of endovascular robotics has been limited because of challenges such as a lack of compatibility with standard devices, a lack of haptic feedback, a need to place interventional devices manually, and complex user interfaces.

The aim of the present study was to evaluate the safety and efficacy of the SENTANTE endovascular robotic system (UAB Inovatyvi Medicina), a next-generation robotic system designed to address these limitations, in performing peripheral endovascular procedures.[5] The robotic system consists of a bedside unit that manipulates the endovascular devices in the operating room and a workstation located outside the operating room that controls the bedside unit according to operator input. The robotic system is capable of the fully remote delivery and manipulation of standard catheter-based devices, including wires (0.014, 0.018, and 0.035 inches), sheaths (2-8 F), and the fully remote placement of interventional devices, including balloons, stents, plugs, and coils. The bedside unit can manipulate up to 3 endovascular devices simultaneously, one inside the other (over the wire) (**Figure 1A**). The remote workstation, which controls the bedside unit, uses conventional endovascular devices as the user interface (**Figure 1B**). The devices at the workstation are manipulated by the operator and are subsequently replicated by the bedside unit in real time. The bedside unit measures device-vessel resistance within the vessels and provides haptic force feedback through the user interface devices. Because the input devices at the workstation consist of standard endovascular devices that provide haptic feedback, the experience for the operator closely resembles performing the procedure at the bedside.

A single-center, prospective, first-in-human clinical trial was conducted to assess the safety and efficacy of the robotic system in peripheral

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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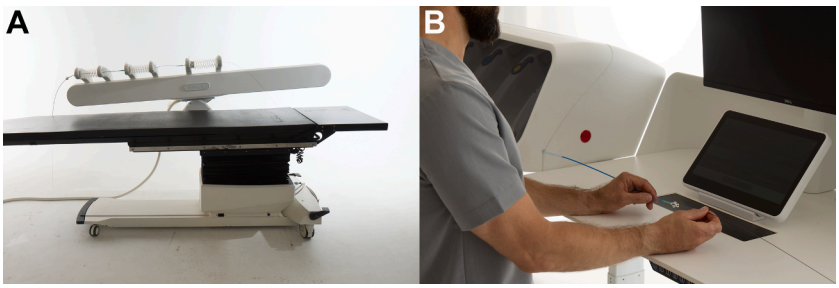
FIGURE 1 The Endovascular Robotic System



(A) The bedside unit of the robotic system, with 3 pairs of cassettes, capable of manipulating up to 3 endovascular devices simultaneously, one inside the other (1 guidewire and 2 over-the-wire catheters). (B) The remote workstation, located outside the operating room, using conventional endovascular devices as the user interface that provide haptic feedback.

endovascular procedures. The study was approved by the local ethics committee. Written informed consent was obtained from each participant.

Between July 2024 and October 2024, 10 patients (mean age 67.1 ± 10.91 years, 3 women) underwent 10 diagnostic and 11 therapeutic procedures. Access was obtained to the common femoral artery under ultrasound guidance, providing retrograde access in 8 patients and antegrade access in 2 patients. The target lesion was reached using a crossover approach in 2 patients.

Diagnostic procedures involved the aortic arch (n = 1), renal arteries (n = 1), aortoiliac arteries (n = 6), and infrainguinal arteries (n = 2). Five patients underwent stenting of the common iliac artery (stenotic lesions of 60%, 75%, and 90%), with 1 patient undergoing additional concomitant stenting of the external iliac artery (80% stenosis) and percutaneous transluminal angioplasty (PTA) of the deep femoral artery (70% stenosis). One patient underwent PTA of the superficial femoral artery at 2 locations (70%-80% and 90% stenoses), and 1 patient underwent PTA of the tibioperoneal trunk (70%-80% stenosis). One embolization procedure was performed using an Amplatzer Vascular Plug (Abbott Cardiovascular), targeting the left internal iliac artery.

For diagnostic procedures, median procedural time was 17.50 minutes (Q1-Q3: 13.75-31.25 minutes), median fluoroscopy time was 2.78 minutes (Q1-Q3: 0.52-4.17minutes), and median injected contrast volume was 15.00 mL (Q1-Q3: 10.00-22.50 mL), respectively. For therapeutic procedures, median procedural time was 15.00 minutes (Q1-Q3: 10.00-25.00 minutes), median fluoroscopy time was 3.23 minutes (Q1-Q3: 2.37-4.25 minutes), and median injected contrast volume was 20.00 mL (Q1-Q3: 7.00-30.00 mL), respectively.

Technical and procedural success was achieved in all cases. Clinical success was achieved in all patients, with no adverse events. None of the procedures required manual assistance or conversion to standard manual procedure, excluding loading and removal of endovascular devices on the robotic system. The average patient radiation exposure was 120 ± 154.13 mGy (maximum 664 mGy). Operator radiation exposure was significantly reduced from an average of 0.95 ± 0.68 to 0.02 ± 0.04 μSv ($Z = -115.5$; $P < 0.0001$), on the basis of a comparison of a reference dosimeter positioned behind a lead x-ray shield in the operating room and a dosimeter in the chest pocket of the operator worn without lead aprons.

The present study demonstrates the potential of a robotic system to perform peripheral endovascular procedures fully teleoperated, including remote stent placement, embolization material deployment, and balloon inflation. By performing procedures fully remotely, radiation exposure to operators can be reduced to near zero. Additionally, this capability could expand access to lifesaving interventions, such as thrombectomies for stroke treatment, in areas where specialized expertise is not available. Larger trials to confirm the safety and efficacy across different clinical scenarios and comparative studies with traditional manual interventions are called for.

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