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Perspectives on Remote Robotic-Assisted Stroke Treatment: A Commentary Paper

 Arturo Consoli,  Nicole Mariantonia Cancelliere, Guillaume Charbonnier,  Julian Spears,  Thomas R. Marotta, and  Vitor Mendes Pereira

ABSTRACT

SUMMARY: The proved feasibility of robotic-assisted endovascular treatment of intracranial aneurysms has stimulated the idea of a potential application of remote robotics for the treatment of acute ischemic stroke. The possibility of developing a more advanced remote-controlled robotic system capable of performing a complete mechanical thrombectomy procedure would help bridge the health care gap of lack of technical expertise in isolated areas. This possibility could allow a more equitable access to mechanical thrombectomy to a larger number of patients and be a breakthrough for acute ischemic stroke care worldwide. Many aspects around the technical, human, financial, and regulatory requirements should be discussed to implement remote robotic-assisted procedures. In this State of Practice article, we aimed to outline the major challenges that must be considered, as well as proposed solutions. However, different solutions may be applied in different health care systems on the basis of the availability of human and financial resources.

ABBREVIATIONS: AIS = acute ischemic stroke; GA = general anesthesia; MT = mechanical thrombectomy; RRAP = remote robotic-assisted procedure

The development of endovascular robotics in the past decade may represent a major advance in minimally invasive treatment of vascular diseases. Some advantages have been previously described, such as the reduced radiation exposure and orthopedic strain on the operators,¹⁻³ as well as enhanced technical accuracy and precision.⁴ In 2019, embolization of an intracranial aneurysm using the Corindus CorPath-GRX system (Siemens) marked the first human robotic-assisted procedure in the neuroendovascular field.⁵ This soon stimulated thought and discussion of a future application for remote robotic-assisted procedures (RRAPs) for acute ischemic stroke (AIS) treatment.^{1,6-8} The aim of this article was to discuss what additional challenges should be considered to build a proper roadmap for new generations of robotic systems and remote procedures. We propose a streamlined discussion on the following topics: geosocial unmet needs, remote site preparation and remote team selection, procedural challenges, training, postprocedural management, and regulatory issues.

Geosocial Unmet Needs

One of the main drivers for the development of remote robotic neurointerventional procedures is to address the unequal access in AIS care to mechanical thrombectomy (MT) for patients living in isolated or rural territories. Indeed, most United States^{9,10} and European populations do not have timely access to MT treatment, particularly those living in rural areas.^{11,12} This geographic problem is exacerbated in larger countries with wider distances between cities. The inhomogeneous geographic distribution of stroke centers,¹ the risk of creating new low-volume centers,⁷ the challenges of low-income countries for the needed expertise,⁴ and the lack of human resources are the most accredited causes of this inequality. Therefore, the implementation of RRAP could be considered a potential response to this inequality. However, several issues must be addressed before bringing RRAP for stroke to actuality.

Procedural Challenges

Telepresence System. The physical distance between the remote operator and bedside team will demand effective real-time communication between sites. A telecommunication system that can reliably transmit audio and visual information between sites, including the live radiographic imaging, will be required for the remote operation to be performed safely. Minimum telepresence system (Cisco) requirements will need to be defined, such as the number and positions of cameras and microphones to give the operator full confidence and maximum safety during the intervention. We suggest a minimum requirement of a moveable,

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side camera above the patient to allow the remote operator to assess the condition of the catheters and devices, to monitor the incision site, and to assess the patient for changes in symptoms. An ideal setup would also include a camera for room view and a second side camera to visualize the robotic arm and supervise loading and unloading maneuvers and perfusions. Also, a private audio feed between the remote operator and bedside technologist will be important to effectively communicate the next steps of the procedure, such as when to exchange devices. A room microphone and speaker may be useful to provide the remote operator additional information on the room environment and the possibility of communicating to the whole team or other team members than the bedside technologist. We strongly believe that these challenges should not be overlooked and should be balanced with the safety limits of defined transmission lag.

Angiographic Imaging Control. During a neuroendovascular procedure, the C-arm can be controlled by the local physician or an x-ray technologist. Fluoroscopy and intermittent DSA runs must be acquired for navigation, and appropriate working projections must be selected to facilitate navigation through tortuous vascular anatomy. Communication of these desired processes may be more challenging in a remote scenario, so the idea of providing remote control of the angiographic system to the remote physician is suggested to make procedures faster, reduce the radiation dose (for both the patient and the bedside technologist), and improve safety. Autonomous control of working projections by an intelligent system may also aid faster navigation, though no specific solutions are currently available.

Robotic System. Finally, the minimum requirements of robotic capabilities should be considered for maximum remote safety and success. The current version of the Corindus CorPath-GRX system allowed simultaneous control of only 1 microcatheter with 1 guidewire or device. This control means that a local physician was required to perform navigation of the aortic arch to place the guide catheter in the internal carotid or vertebral artery at the neck. It also precludes the ability to use a combined approach or contact aspiration for MT.^{2,13} Robotic control of a full triaxial system composed of 4 devices should be considered for maximum safety in the next-generation robotic systems. Additional functionality such as control of aspiration or inflation of balloons should also be considered to give the physician full control of the stroke intervention.

The robotic-assisted approach for neurovascular disease treatment has been mostly used for intracranial aneurysm embolization, and for these procedures, all patients were under general anesthesia (GA).^{4,5} The choice of GA for future RRAPs, or at least in the early phases, is suggested to ensure patient safety during the procedure, because movement of the patient with a fixed robotic system may carry an increased risk of dissection. A secondary advantage of using GA would be to use the imaging to improve artificial intelligence-based algorithms for automatic correction of the robotic movements, which require minimum motion artifacts. Indeed, engineering and mechatronic implementation are adding a large contribution to the robotic-based approach with encouraging results in terms of automated

navigation to reduce the occurrence of unexpected movement of the devices,³ which may be of great use in a remote setting.

Connectivity. The RRAP will be entirely based on connection systems ensuring a reliable, fast, and stable transmission of data. Although RRAPs have been performed, none of these ever included a remote neuro-endovascular procedure. Five RRAPs of percutaneous coronary interventions were successfully performed in India in 2018,¹⁴ using an optical fiber connection with the CorPath-GRX system, whereas 5G has been successfully used for orthopedic screw placement between Beijing and Zhejiang through the TiRobot system (Tinavi Medical Technologies Co., Beijing, China).¹⁵ Some groups have tested latency requirements for RRAP, and thresholds of non-perceptibility ranged between <400¹⁶ and <250 ms;¹⁷ however, these should be validated in the context of a stroke procedure because neurosurgical procedures carry higher risks. Furthermore, in our opinion, these studies were incomplete because latency is not the only metric that will define safety. Other parameters such as bandwidth, jitter, the use of virtual private networks, and the transmission pathway affect the network performance^{1,8} and should be comprehensively studied. We foresee a rigorous testing in each new remote location to find the most reliable and effective connectivity network to link to the operator site with an acceptable latency (<250 ms). A primary network should be used as a default and tested constantly, and a secondary network should be in place in case the first one fails during a procedure.

Nevertheless, several questions should be addressed before accurately assessing latency. These include but are not limited to the telecommunication system requirements, the quality of the angiographic images to be transferred, the transmission pathway, the digital weight of the new-generation robot control, and other potential tools to be added (such as the remote C-arm control). Indeed, these will determine the number of data packages to be transmitted, which will affect overall latency.

Remote Site Preparation and Team Selection

The preliminary in situ development of robotic-assisted procedures helped to define the basic requirements for a novel approach to neuroendovascular procedures, which demanded new workflows and a procedural setup.⁴ Although RRAPs could spread the expertise of interventional stroke to remote areas in need,⁷ a physical distance would be added between the robotic operator and the remote site. Thus, this would require the presence of a stroke care environment (including a Stroke Unit, Intensive Care Unit, and vascular neurology support) at the remote site to properly manage the acute and subacute phases of patients with AIS. Rehabilitation services should also be available to assist patients who do not make a full recovery after endovascular treatment.¹⁸

Future versions of endovascular robotic systems should overcome the limitation of current, approved robotic systems that do not support all steps of a MT procedure, thus requiring some steps to be performed manually by an on-site operator, including obtaining vascular access, navigation of the guiding catheter, stent placement, and/or angioplasty maneuvers.^{1,2,7} Some authors have suggested that any type of interventionalist, not necessarily on-site but on-call, could be a plausible solution.⁷ Some of these tasks, such as obtaining vascular access, could be performed by

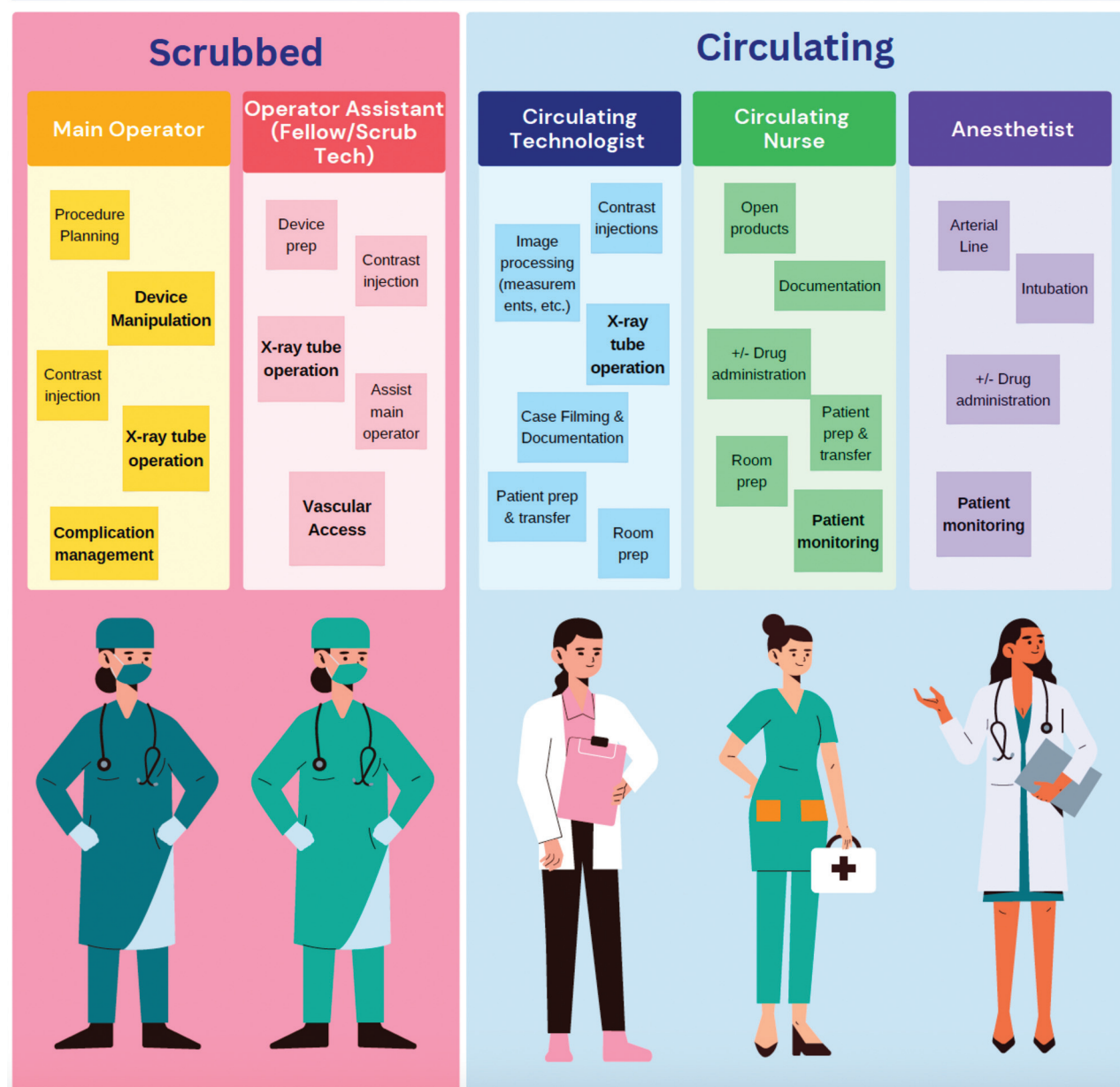


FIG 1. Current scenario and description of the roles of each member involved in neuroendovascular procedures for acute stroke.

another qualified member of the on-site team. In a remote scenario where the operating physician is not in the room, there will need to be a shift in roles for the bedside team. In our opinion, the core team for RRAPs should include the following: a remote, experienced robotic operator, a trained robotic bedside technologist, a supporting physician, an anesthesiologist, and a stroke neurologist locally or on telestroke (<https://www.mayoclinic.org/tests-procedures/stroke-and-telemedicine/about/pac-20395081>). In this new scenario, the remote operator would be linked to a local “clinical coordinator” or telestroke for patient selection and to a “technical coordinator” (the bedside technician) to plan the

setup for the procedure. Our suggestions for the various team members’ roles in a local-versus-remote robotic-assisted scenario are shown in Figs 1 and 2.

Training

RRAP will require more rigorous training for both the remote operator and the on-site team. It is mandatory to create a solid bond of trust⁶ and develop effective communication between the 2 teams to ensure proper management during the procedure. We suggest that simulated rehearsals be regularly performed to maintain familiarity with the robotic system and the remote workflow.

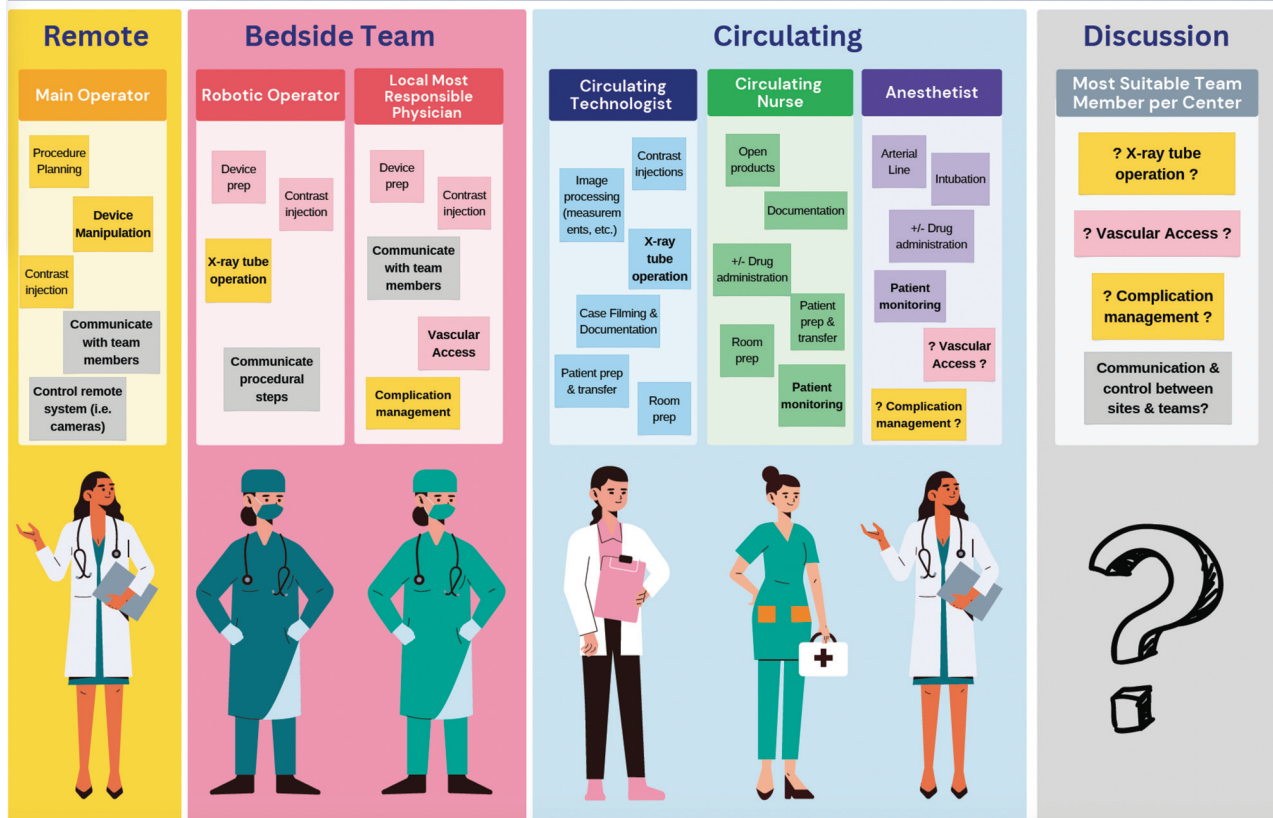


FIG 2. Suggested members and role changes to support remote robotic stroke procedures: a proposal of a new distribution of roles and tasks.

These will also be important to establish communication protocols, verify proper functioning of the robotic system, and practice safety protocols such as the workflow for manual takeover.⁵ Simulation-based technology could represent a viable solution for training to flatten the learning curve and reduce technical complications.¹⁹ However, a precise logbook and a definite training protocol²⁰ will be necessary for future RRAPs.

Regulatory Hurdles

Although the technical feasibility of RRAPs is currently being tested with some encouraging results, several regulatory considerations must be discussed. State licensing and facility credentialing have already represented a limitation for remote imaging in the past and should be considered for remote procedures as well. Although the cost-effectiveness of RRAPs cannot yet be assessed due to lack of data, some simulation-based models have suggested that the introduction of remote stroke care has the potential to improve clinical outcomes and reduce stroke-related costs to the health care system.²¹

Human feasibility studies should be performed after rigorous technical and clinical validation, and clinical trials for stroke RRAP treatment could then be designed with the support from the regulatory bodies to show the noninferiority of remote procedures.⁶ Indeed, the management of potential intraprocedural complications would require the presence of an on-site or on-call

interventionalist,⁷ whereas clear indications about the medical/technical responsibility will need solid and constructive discussions.¹ Furthermore, comprehensive guidelines will necessarily have to be redacted under the guidance of the international scientific societies, to account for all the possible political and regulatory issues.

CONCLUSIONS

We are not yet ready for prime time. There are various considerations in preparation for RRAPs, including telecommunication system and robotic system requirements for increased remote control capabilities, such as triaxial control, and understanding of safety limits. Remote stroke treatment simulations should be performed before a clinical attempt. The potential benefit of remote stroke intervention is real, and it can be transformative. Remote areas in countries with vast geographies or in developing countries with lack of centers and professionals may have a unique opportunity to finally have access to acute stroke care.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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