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The Effectiveness of Interventional Radiology Procedures in Minimally Invasive Treatments:

(Critical Review)

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Abstract

Background: Minimally invasive endovascular techniques have become crucial in medical practice for treating various vascular disorders. These techniques utilize the blood vessels as pathways to reach distant areas, allowing for precise administration of medications like chemotherapy or radiation therapy. However, there are challenges that hinder a more extensive adoption of an all-endovascular approach, including the complexity of vascular anatomy, difficulty accessing small blood vessels, vulnerability of diseased vessels, need for emergency procedures, prolonged exposure to X-ray radiation, and patient-specific factors like coagulopathy. Fresh innovations are needed to overcome these limitations.

Aim of Study: This study aims to explore the current status of small-scale robots in endovascular applications. It compares their potential benefits to existing tethered clinical devices and delves into technological obstacles and clinical specifications necessary for the practical implementation of untethered robots inside blood vessels.

Methods: The methods used in this study involve a comprehensive review and analysis of the existing literature on small-scale robots in endovascular applications. The review includes an examination of their potential benefits, comparison with tethered clinical devices, and identification of technological and clinical requirements for practical implementation.

Results: The study highlight the potential benefits of small-scale robots in endovascular applications, including improved precision, wireless control, and autonomous operation. A comparison with tethered clinical devices reveals the advantages of untethered robots. However, there are technological obstacles and clinical specifications that need to be addressed for the practical implementation of these robots inside blood vessels.

Conclusion: In conclusion, small-scale robots show promise for advancing minimally invasive endovascular treatments. They have the potential to overcome existing limitations and establish new benchmarks. However, further technological advancements and consideration of clinical requirements are necessary for their practical implementation.

Key Words: *Minimally invasive – Endovascular techniques – Small-scale robots – Untethered – Blood vessels.*

Introduction

CARDIOVASCULAR disorders remain a significant source of illness and death globally [1]. Various vascular problems, such as vascular damage, atherosclerosis, thrombosis, thromboembolic diseases, and aneurysms, contribute to the high mortality rate. Traditionally, open surgical techniques were used to address most of these conditions. However, the introduction of minimally invasive endovascular techniques has led to a preference for nonsurgical approaches. These approaches offer benefits such as faster recovery times, lower mortality rates during the perioperative period, improved quality of life, reduced hospitalization, and shorter stays in the intensive care unit. Furthermore, endovascular procedures are generally more cost-effective compared to open vascular surgeries. Interventional radiologists have also utilized minimally invasive endovascular techniques to provide innovative local treatment strategies. These include transcatheter chemoembolization, radioembolization, and other ablative techniques. Additionally, endovascular procedures can be used for vascular embolization to treat hemorrhage, as well as benign conditions like benign prostatic hyperplasia and uterine fibroids. Mechanical techniques, such as thrombectomy, can also be performed using these methods [2-4].

Although these treatments are well known and popular, there is always room for improvement in

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the state-of-the-art endovascular techniques. Challenges arise from the need to navigate intricate vascular anatomies that are complicated by tortuosity or diseased arteries, which may be constricted or blocked due to atherosclerosis or thrombosis. Furthermore, the catheter-directed therapy of small vascular disease is often fraught with risks and limited to the administration of pharmaceuticals and microparticles. Recent clinical evaluations indicate that although minimally invasive endovascular procedures have led to a decrease in early mortality, the long-term survival rates of open surgery and endovascular interventions are similar. Additionally, endovascular approaches may necessitate multiple interventions. For instance, the rates of rebleeding or failure after coil embolization of aneurysms can be as high as 47%, necessitating additional procedures. Thrombectomy procedures may need to be done in stages and involve combining different approaches that may take several days. Patients who receive vascular stents may experience restenosis or occlusion, requiring additional procedures such as angioplasty, additional stents, or thrombolysis [5-7].

In recent decades, there has been gradual progress in endovascular procedures, mostly focused on the refinement of catheters with small enhancements, the introduction of more angioplasty balloons, and the advancement of stents. In order to overcome the many constraints of current endovascular treatments, the future advancements in minimally invasive procedures are expected to use robotics, namely small-scale untethered robots. Over the last ten years, there has been a significant surge in the interest around the creation of robotic systems specifically designed for healthcare purposes. Notable examples of advancements in medical technology include devices and platforms for robot-assisted surgery, compliant soft robots, assistive devices, and pill-sized capsule endoscopes for gastrointestinal delivery. These innovations support a growing trend towards medical solutions that are minimally invasive, patient-centered, precise, and personalized [8].

Mobile robots that are not connected to anything, and are smaller than a few hundred micrometers, have the potential to greatly improve the range and effectiveness of minimally invasive endovascular operations and targeted treatments [9]. These robots are able to move through difficult-to-reach blood vessels and perform precise and repeatable diagnostic and therapeutic procedures. Recent advancements have led to the development of small-scale mobile robots that can be controlled remotely (Fig. 1) [10]. However, despite the progress made in combining smart materials and mobility control, these robots often lack a comprehensive design approach that can effectively meet the needs of their intended medical applications [9]. An endovascular microrobot must have a design that can be adjusted to meet the specific needs of the clinical condition. This includes being able to enter the body, track its location in real-time, prevent fouling, operate safely at the intended site, and be retrieved if necessary after the procedure. These aspects are particularly crucial because any malfunction within the circulatory system could quickly worsen and lead to illness or even death due to unintended blockage, puncture, or damage to the blood vessel walls such as tearing and blood clot formation. This is a significant potential limitation for any remotely controlled equipment intended for use inside the vascular system. It is crucial to understand that the tolerance for device failure inside the blood vessels is very minimal, if not nonexistent.

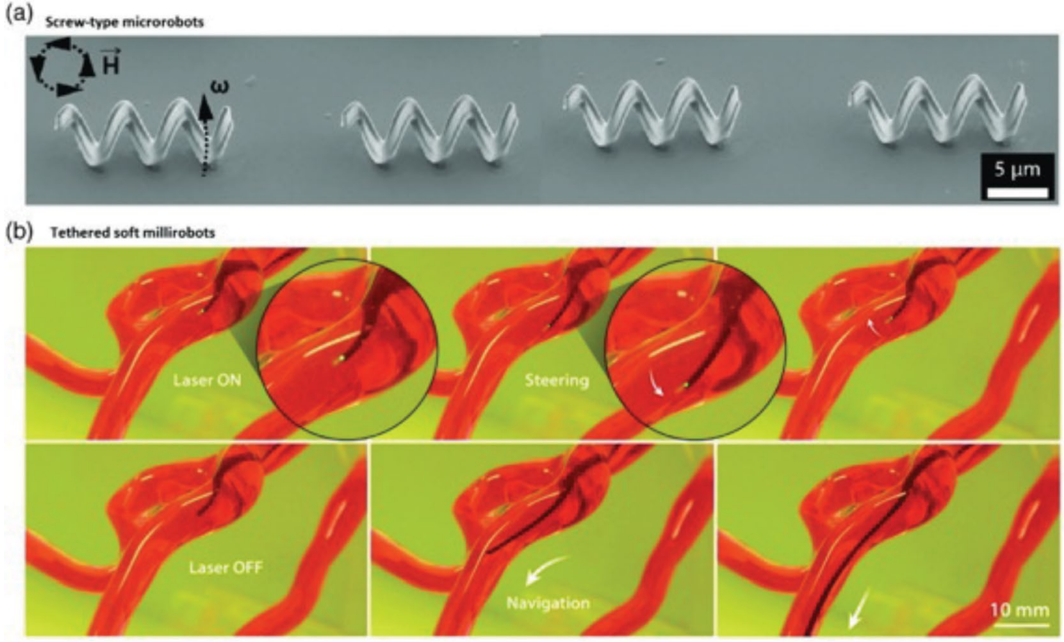

Fig. (1): Miniature robotic designs for possible use in endovascular procedures. (A) Propulsion is achieved by soft polymer screw microswimmers rotating around the primary helical axis.

Aim of work:

In this article, we provide a critical analysis of next-generation endovascular devices that use developing robotic technologies. These technologies have seen a trend towards smaller, untethered, and mobile devices. Smart soft-body designs with exceptional maneuverability are a significant technical accomplishment, surpassing the limitations of tethered catheters in navigating through narrow channels with precise control. In the future, microrobots that have the ability to work autonomously might greatly improve the medical practice of minimally invasive endovascular operations.

Current advancements in tethered endovascular devices:

Endovascular procedures are often conducted with a catheter, which is a long, slender, and pliable tube that may be seen with the use of fluoroscopy. Catheters were initially employed in angioplasty, a procedure developed by Dr. Dotter in 1964, to dilate stenosis using inflatable balloons. These conventional catheters have restricted mobility and flexibility, requiring operators with expertise to skillfully navigate the catheter tip to effectively reach and interact with the desired location. Originally, in the early designs of catheters, a bunsen burner was used at the point-of-care to heat certain sections of the catheter in order to create a bend, which facilitated better catheterization of arteries. Nowadays, catheters with predetermined forms, such as the Cobra catheter, are utilized with a standardized method that suits all patients. The limitations of these tethered devices include challenges in terms of dexterity, safety, and stability while operating on complicated anatomies, as well as the absence of force sensing capabilities. These variables ultimately contribute to the failures and problems of the intervention **[11]**.

Endovascular procedures still primarily rely on two-dimensional live fluoroscopy as the main imaging technique. As a result, the operator loses the very vital knowledge about the 3D structure of the blood vessels. In addition to being able to see, it is crucial for interventionalists to have the ability to feel forces and get haptic feedback. Trainees, particularly those who are new, may have challenges until they acquire the skills to gather and react to these tactile clues. Managing catheters and guidewires may be challenging due to the elongated nature of the catheter. For instance, if the operator spins a catheter that is 150 cm in length, the distal tip should likewise rotate in response, even if it is looped around the body. Therefore, it may not be possible to measure angles when the vector force is oriented differently from the intended direction of movement. Additionally, the configuration and rigidity of the tip play a role in this entanglement. Although rigid catheters have limited flexibility, catheters with soft tips are more challenging to navigate through the vasculature because they lack pushability. If the origin of the targeted artery is too tiny or positioned at a sharp angle, taking into account the simultaneous blood flow, the procedure of catheterization may be prolonged and need several catheters/guidewires, resulting in increased healthcare expenses. This may lead to vascular damage and also increases the use of contrast chemicals, as well as prolonging radiation exposure for both the patient and the operator **[12-14]**.

Teleoperated robotic navigation systems have been developed for these specific purposes. The primary objectives of these systems are to enhance dexterity and accuracy, minimize contact with vessel walls, eliminate radiation exposure, and provide a comfortable working position for the operator. However, a drawback of these teleoperated robotic navigation systems is the absence of haptic or force feedback when manipulating wires, catheters, or devices such as stent deployment, angioplasty balloon inflation, or thrombectomy device usage. Receiving such input is crucial in order to prevent issues. Currently, the feedback is either nonexistent or still in the first phases of development. For instance, the effectiveness of combining haptic feeling with teleoperated robotic-assisted systems is often confirmed by in vitro validation. In order to be implemented in clinical practice, it is necessary to do thorough testing in live animal models, followed by trials with patients **[14]**.

Steerable endovascular catheters were created to enhance the possibilities of catheters. They provide enhanced command and remote manipulation capabilities at the operator's request. The deflection of the distal tip of the steerable catheter may be more precisely controlled using remote control capabilities. As a result, they have enhanced the ease of accessing complex anatomical structures and increased the stability of catheters during procedures. Remotely controllable catheters also allow for the potential of intervening with the patient from a distance (in a different room or even across long distances), leading to less exposure to X-ray radiation for the physician. The primary methods of actuation used in commonly used steerable catheters are pull-wire (tendon drives), smart material-actuated, magnetic, and hydraulic drives. These catheters have proven to be highly beneficial in various minimally invasive clinical procedures, such as cardiac arrhythmia ablation and targeting the peripheral vasculature. However, complications related to the use of tethered devices include perioperative bleeding, thrombosis, perforation, rupture, dissection, restenosis, and endovascular leaks **[12,15,16]**.

The Food and Drug Administration has granted approval for the use of several robotic navigation systems in the realm of interventional medicine. The Sensei X and Magellan, developed by Hansen Medical in Mountain View, CA, USA, are examples of robotic catheterization systems that have been used in clinical settings. The Sensei robotic system utilizes tendon drives to manipulate its outer sheath, which is equipped with catheters for performing tasks like as ablation or mapping. The operator may manipulate tendon drives using either a joystick or navigation buttons. The Magellan Robotic System, derived from The Sensei robotic system, has been employed in cardiac electrophysiological applications [17] and endovascular aneurysm repair [18]. It utilizes a reduced-size outer guide catheter to navigate within the vasculature under 2D fluoroscopy. An inherent limitation of this technology is the absence of haptic feedback integration. The system's application areas include a wide array of endovascular treatments, such as diagnostic cerebral angiography. However, its limited flexibility to navigate steep corners may render it unsuitable for neurovascular operations. Magnetic catheters provide more feasible alternatives in the cerebral vascular bed because to their decreased stiffness, which allows for enhanced maneuverability at acute angles. Furthermore, the occurrence of difficulties due to catheter injuries may be minimized by using catheters that have a lower level of rigidity. An optimal catheter system should also tackle size constraints for use in the cerebral vasculature [19,20].

The Niobe robotic magnetic navigation system (Stereotaxis, St. Louis, MO, USA) is another commercial device that uses two permanent magnets to generate a magnetic field for controlling the tip of the magnetic catheters/guidewires. This system has also been used in investigations involving the electrical activity of the heart and in the treatment of diseases affecting the arteries of the heart and other parts of the body. Likewise, the Amigo system (Catheter Precision) is a mechanically operated system designed for mapping and ablation operations in cardiac electrophysiology. This robotic device enables the remote control of standard electrophysiology catheters, allowing them to be directed in three degrees-of-freedom: insertion/withdrawal, rotation, and tip deflection [21,22].

The CorPath GRX robotic-assisted platform, an advanced version of the CorPath 200, offers improved control and precision in manipulating medical devices, particularly after reaching the target site. However, a physician is still necessary for tasks such as vascular access, initial catheter guidance, device deployment, and additional personnel are needed to assist with the procedure. It is important to examine the benefits that these robotic systems may provide, and more measures should be taken to improve their setup time, interoperability with existing equipment, and minimize healthcare costs. Sajja et al., [23] highlighted that using the robotics system for emergency medical situations like stroke would be harmful until more advanced systems are developed for prompt use. They made this observation while assessing the platform's effectiveness in performing elective diagnostic cerebral angiography and carotid artery stenting in ten patients. Ultimately, we recognize that these robotic systems have significant promise, contingent upon the occurrence of groundbreaking advancements in these technologies.

While recognizing the newness and prospective benefits of these robotic systems in terms of skill and accuracy during medical operations, there are still significant limits. Prompt access to medical treatment is crucial during crises, and implementing these systems may need a certain amount of time and substantially prolong the duration of the operation. For instance, in a particular study, the time required for equipment setup and sterile draping amounted to 70 minutes. However, this duration is considerably reduced when using conventional methods. Consequently, it would be challenging to introduce a robotic system for urgent medical procedures, particularly in cases involving hemorrhage, stroke, and myocardial infarction, where the speed and effectiveness of the intervention directly impact the clinical outcome. Moreover, these systems need a considerable amount of supplementary training for operators and personnel to use. Additionally, the exorbitant expense of acquiring, maintaining, and operating these systems in comparison to traditional methods poses a huge obstacle to accessibility. It is important to mention that there is a lack of tactile input during these tethered robotic procedures, which might result in a negative experience for physicians [24,25].

Small-scale untethered mobile robots for endovascular interventions:

Vascular and interventional radiology has been widely acknowledged in several medical facilities worldwide for its potential to provide improved results, reduced operation times, and cost savings. Nevertheless, there are other problems associated with tether-based endovascular therapies that must be addressed via the development of sophisticated devices and procedures. An effective strategy for addressing this dilemma involves using tiny, autonomous mobile robots for performing endovascular procedures. Therefore, the forthcoming endovascular gadgets that use advanced robotic systems are expected to alleviate and address the many challenges that doctors already encounter [26,27].

Vascular interventionalists often encounter technical and anatomical challenges when treating patients. The successful outcome of vascular interventions heavily relies on the ability to maneuver tethered devices and employ techniques with skill and accuracy, particularly when navigating through intricate vascular anatomies. If endovascular operations are not executed with skill and accuracy, they have the potential to cause significant difficulties. Therefore, the effectiveness of modern endovascular interventions mostly relies on the skill and expertise of the doctors executing these operations. One significant obstacle in using small-scale robots that are not connected to anything is to achieve the highest level of skill and precision; it is not feasible for humans to directly engage with these microrobots. Scaling the force feedback teleoperation is a feasible method to aid the interventionalist working inside the blood vessels [16,28-30].

To achieve entry into vascular beds, one might consider deploying at different locations. For example, in endovascular arterial procedures, the common femoral artery is typically the preferred access site for deploying conventional tethered devices. However, certain conditions such as iliac tortuosity, inadequate iliofemoral diameter, or aortoiliac vascular disease can restrict safe and successful access to the abdominal or thoracic vasculature. In particular, arterial occlusive diseases that have been aggravated by calcification may require advanced techniques and devices for navigation. Additionally, manipulation of endovascular devices can lead to vasospasm and injury in the inner lining of the arteries, potentially resulting in thrombosis. Moreover, accessing and reaching the delicate and intricate cerebral vascular bed can be extremely challenging. Any error or accident involving the catheter or guidewire in the blood vessels of the brain may lead to serious health problems and perhaps deadly consequences [12,31-34].

Until recently, the development of robotic designs for vascular interventions has been hindered by challenges in miniaturization. However, a new type of soft robot called ferromagnetic soft robots, which are controlled by magnets, has been created and tested in a simulated cerebral blood vessel system with multiple aneurysms. Kim et al., [33] demonstrated that this ferromagnetic robot, which is self-lubricating and operates at a submillimeter scale, has the ability to steer in all directions and navigate through intricate settings. In order to minimize friction and other difficulties, the researchers developed a hydrogel skin for the robot. This skin consists of a thin layer of hydrated and crosslinked polymers. Furthermore, the act of equipping these robotic devices with diverse therapeutic substances and then deploying them in afflicted regions has the potential to enhance the range of therapeutic and diagnostic tools available to interventional radiology. These robotic systems possess considerable promise to facilitate operations that were previously deemed almost impossible, particularly in the field of neurovascular applications. Stroke management, whether caused by intravascular hemorrhage or acute thromboembolic event, may include the use of minimally invasive radiological procedures done by robots capable of swiftly and accurately navigating to the targeted area without causing harm. Helical robots have been used in a different study to stimulate blood clots in a controlled environment using magnetic force and ultrasound imaging. This was done to explore the possibility of employing these robots for thrombolytic treatment [34].

While the helical or ferromagnetic design principles seem to be promising, there are significant questions about their actual viability. Medical crises arise when the pathophysiology of a disease is linked to atherosclerosis or thromboembolic events, such as stroke, pulmonary embolism, and myocardial infarction. These conditions need prompt management. The criterion of time to groin puncture is routinely recorded and reported in clinical practice [35]. Consequently, the current employment of these microrobots and similar technologies would not be feasible. Modifying atherothrombotic plaques may be risky due to their inherent instability and resistance to degradation by medicines like tissue plasminogen activator (tPA). Because of their diverse composition, it would be difficult to use these spiral and other robots to stimulate arterial blockages and the potential for fragmentation further increases the danger of worsening the ischemic illness. Furthermore, the navigation of these large devices to the desired blood vessels, the lack of control over the diameter of the robotic motion which may lead to damage and rupture of the vessel walls, and the challenges in safely retrieving these devices all contribute to the increased risk associated with these treatments.

Imaging and tracking:

Accurate monitoring of robots navigating through blood vessels is crucial to ensure safety, dependability, and precise execution of endovascular procedures [37]. Consequently, the development of a miniature robot must always consider its compatibility with existing medical imaging techniques and tracking methods tailored to specific medical uses. The majority of small-scale robotic experiments have shown their functionality using optical microscopes or other nonvascular technologies [37,38]. Nevertheless, these approaches have not yet been evaluated in an in vivo, endovascular context. An appropriate imaging and tracking technique should also be able to work well with the actuation approach. Physician proficiency in clinical imaging modalities is essential for quickly adapting to new procedures. The broad availability and convenient accessibility will decrease the cost of adoption, enabling extensive use of robots in clinical practice. The spatial resolution, image capture rate, and penetration depth of the device may be interconnected and may be most effectively adjusted for a specific medical job. When considering the medical needs and interdependent aspects of imaging modalities, it is crucial to assess the robotic design factors, including size, material type, and localization accuracy.

Medical practitioner acceptance:

An essential factor to contemplate in the creation process of any biomedical equipment is its acceptance by the physician or other pertinent healthcare practitioners, a consideration that is sometimes disregarded or not taken into account. An ideal small-scale endovascular robot should include intuitive and user-friendly controls, be cost-effective, and outperform the present level of medical practice in performing interventions. The learning curve for operating these small-scale robots should be considerable.

Conclusion:

Although there have been notable technical advancements, robotic systems still encounter substantial difficulties when used in therapeutic settings. Increased cooperation between physicians and engineers will enhance ongoing efforts and optimize the results of scientific study. The crucial factor in creating a robotic system that can be widely used in clinical settings is effective collaboration between engineers and clinicians. This collaboration allows engineers to get a deeper understanding of the issues faced by clinicians, and in turn, design targeted solutions for these challenges. Untethered soft robots have the potential to serve as advanced instruments for image-guided minimally invasive procedures. However, there are still significant tasks that need to be accomplished before they can be effectively used in veins and arteries.

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فعالية إجراءات الطب الإشعاعى التداخلى فى علاجات الحد الأدنى للغثيان: مراجعة نقدية

الخلفية: أصبحت التقنيات القليلة التدخلية القليلة الغثيانية حاسمة فى الممارسة الطبية لعلاج مختلف اضطرابات الأوعية الدموية. تستخدم هذه التقنيات الأوعية الدموية كممرات للوصول إلى مناطق بعيدة، مما يسمح بإدارة دقيقة للأدوية مثل العلاج الكيميائى أو العلاج الإشعاعى. ومع ذلك، هناك تحديات تعيق اعتماد أكبر على نهج كلى للأوعية الدموية، بما فى ذلك تعقيد تشريح الأوعية الدموية، صعوبة الوصول إلى الأوعية الدموية الصغيرة، ضعف الأوعية المريضة، الحاجة إلى إجراءات الطوارئ، التعرض المطول لأشعة الأشعة السينية، وعوامل محددة للمريض مثل اضطراب التخثر. هناك حاجة إلى ابتكارات جديدة للتغلب على هذه القيود.

هدف العمل: يهدف هذا الدراسة إلى استكشاف الوضع الحالى للروبوتات بمقياس صغير في تطبيقات الأوعية الدموية. يقارن فوائدهم المحتملة بالأجهزة السريرية المرتبطة الموجودة ويستكشف العقبات التكنولوجية والمواصفات السريرية الضرورية لتنفيذ عملى للروبوتات غير المرتبطة داخل الأوعية الدموية.

الطرق: تتضمن الطرق المستخدمة فى هذه الدراسة استعراضاً وتحليلاً شاملًا للأدبيات الحالية حول الروبوتات بمقياس صغير فى تطبيقات الأوعية الدموية. يتضمن الاستعراض فحصًا لفوائدهم المحتملة، والمقارنة مع الأجهزة السريرية المرتبطة، وتحديد المتطلبات التكنولوجية والسريرية للتنفيذ العملى.

النتائج: تسلط الدراسة الضوء على الفوائد المحتملة للروبوتات بمقياس صغير في تطبيقات الأوعية الدموية، بما فى ذلك تحسين الدقة، والتحكم اللاسلكى، والتشغيل الذاتى. يكشف المقارنة مع الأجهزة السريرية المرتبطة عن مزايا الروبوتات غير المرتبطة. ومع ذلك، هناك عقبات تكنولوجية ومواصفات سريرية يجب معالجتها لتنفيذ هذه الروبوتات داخل الأوعية الدموية عملياً.

الاستنتاج: فى الختام، تظهر الروبوتات بمقياس صغير واعدة لتعزيز علاجات الأوعية الدموية القليلة التداخلية. لديهم القدرة على التغلب على القيود القائمة وإنشاء معايير جديدة. ومع ذلك، هناك حاجة إلى تطورات تكنولوجية إضافية ومراعاة لمتطلبات السريرية لتنفيذها عملياً.