

Review

Review of New Master/Slave Catheter Driving Vascular Intervention Robot System: Intervention Radiologist's Perspective

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The interventional procedure is a percutaneous treatment modality using various devices such as a guide-wire and a catheter under a minimal incision. It is usually done under a fluoroscopy (X-ray radiography) guidance, therefore the operator would be exposed to X-ray irradiation. Recently, a new procedure using a master-slave robotic system is proposed for the intervention procedure, especially in the era of vascular disease. Many state of art intervention robots are under development and this approach can drastically reduce radiation exposure by replacing human effort by a robotic system for high radiation exposure procedures. However, robotic intervention is still more expensive and needs more efficient end effector and easier human interface for a safer and faster procedure. This article provides a comprehensive summary of vascular intervention and necessity of the vascular intervention robot system.

Key words: Vascular, Intervention, Master-slave, Robot, radiation

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Received 4 October 2016

Revised 21 October 2016

Accepted 26 October 2016

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WHAT IS THE VASCULAR INTERVENTIONAL PROCEDURE?

The interventional procedure is a new treatment modality that treats specific disease via percutaneous, minimally invasive manipulation using various devices such as a guide-wire, catheter, balloon, and stent under the various imaging modalities such as ultrasound, fluoroscopy (X-ray radiography), computed tomography and magnetic resonance image. It does not need a large surgical incision. Its advantages include reduced bleeding due to a minimal skin incision, rapid patient recovery, and few possible complications because of local rather than general anesthesia. It is classified as nonvascular and vascular procedures (Fig.1)[1].

The vascular interventional procedure is used for treatment of arterial and venous diseases and cancers. The technique involves access to the target organ by percutaneous insertion



Fig. 1. Picture of intervention procedure: It is usually performed under the fluoroscopy (X-ray radiography) after a full surgical drape of the patient and operator.

of a catheter of 1-7 mm diameter through blood vessels under ultrasound or fluoroscopic guidance. The vascular interventional procedure can be applied to liver tumors,

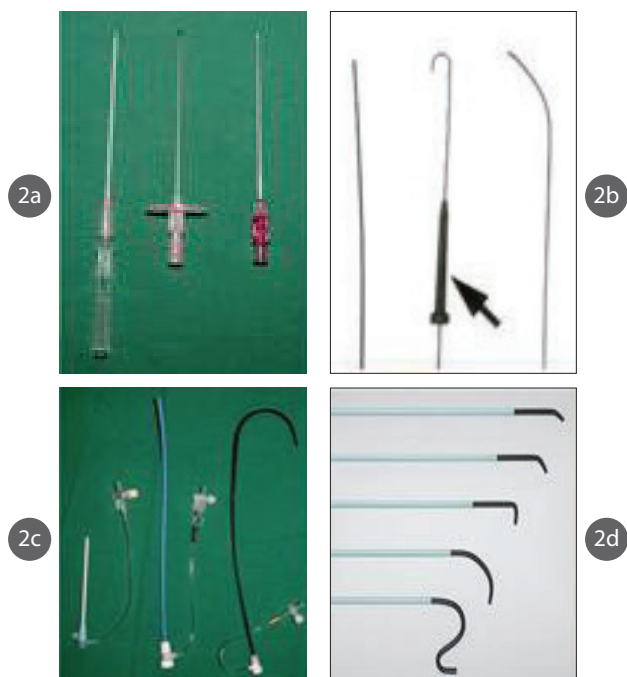


Fig. 2. Intervention Devices; (a)Puncture needle, (b)guide wire, (c) introducer sheath, (d)catheter

Table 1. Basic configuration of the devices needed for vascular interventional procedure

Device	Function
Vascular puncture needle	Penetrate the vessel wall to insert a device Usual target artery: common femoral artery that is palpable typically in the groin and easily detected on ultrasound.
Guide wire	Provides guidance for inserting the catheter safely
Introducer Sheath	Facilitates the insertion and replacement of the catheter, and prevents vascular damage that can result from the insertion or advancing and retracting process of catheter
Catheter	It has an external diameter of 3-8 French (1.0-2.7 mm) and a hole of approximately 0.010-0.035 inch diameter in which the angiographic contrast agent can pass through. It can be inserted typically through the introducer sheath along the guide wire.

arterial bleeding, various vascular occlusion or stenosis, uterine fibroid embolization, and its scope of application is currently expanding.

Fine medical device manufacturing made possible by the development of precision machining technology has led

to several advances in medical devices for interventional procedures. Introducer catheter or sheath, catheter, and guide wire are the basic devices of the technique, which have the purpose of injecting contrast agent to a desired blood vessel for diagnostic angiography. Devices for treatment include catheter for radiofrequency ablation, stent, and balloon catheter and are modified such that an electrode is attached to the catheter tip, the stent is mounted on the inside, or a balloon is attached to the middle part, respectively (Fig.2)(Table 1) [2].

STEP-BY-STEP INSTRUCTIONS FOR THE VASCULAR INTERVENTIONAL PROCEDURE.

After puncturing the vessel under an ultrasound guidance or by palpating the artery, an introducer catheter is inserted and fixed to protect the blood vessel from trauma. After the guide wire and catheter are inserted as shown in the Figure 3, catheter and guide wire are navigated to select the target vessel. The direction of the guide wire is determined by the rotation along the angulation of the blood vessels. Subsequently, the catheter (usually 5 French=1mm in out-diameter) is inserted or rotated along the guide wire, and the process is repeated until reaching the target vessels. In order to reach a smaller vessel, a catheter with a 3-French smaller diameter (microcatheter) and a micro-guide wire are inserted inside of the main 5-French catheter, and the direction is determined by the insertion and rotation of the guide wire for microcatheter as with the catheter; and the microcatheter is then inserted along the guide wire. Finally, angiography is performed or the therapeutic drug is delivered by injecting the contrast agent or drug through the catheter or the microcatheter after removing the guide wire [3,4].

THE VASCULAR INTERVENTION ROBOT - WHY IS IT NEEDED?

1. Problems of the vascular interventional procedure

1) Excessive radiation exposure

A survey of Korean Society of Interventional Radiology indicates that the average radiation exposure time in one procedure of transcatheter arterial chemoembolization therapy of hepatocellular carcinoma, which is one of the most frequently performed intervention procedure in Korea, is 13.3 ± 8.07 minutes; and the radiation dose per procedure is approximately 03-0.8 mGy, which is approximately 0.2% of radiation exposure allowance for a year. Each interventional

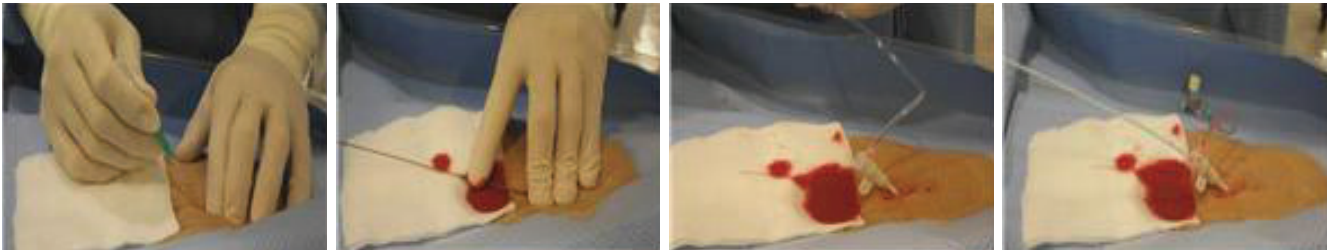


Fig. 3. Basic vascular intervention procedure. (a) Vascular puncture: The needle is used to puncture a femoral artery that is palpable typically in the groin under an ultrasound-guidance or palpation examination. (b) Insertion of the guide wire: The guide wire is inserted through the puncture needle. (c) Insertion of the introducer catheter: The introducer catheter is inserted along the guide wire. (d) Insertion of the catheter: The catheter is inserted along a guide wire through the inside of the introducer catheter.

operator in large domestic hospitals performs approximately ≥ 500 transcatheter arterial chemoembolizations annually; hence, it is imperative to minimize the radiation exposure of the operators. As the radiation exposure standard is stricter in developed countries, active efforts are made to reduce the operators' and assistants' radiation exposure [5].

2) Operators' physical stress caused by the radiation shielding clothing and shielding devices

- The prolonged procedures that require shielding clothing at about 10 Kg, lead glasses, thyroid protectors, etc. (Fig.4) cause physical load and stress on neck, back, and knee joints of the operator with consequent increases in frequency of bone and joint diseases.



Fig. 4. Radiation protection equipment. Clothing at about 10 Kg, lead glasses, and thyroid protectors.

3) The procedure conditions vulnerable to infections

Patients enter and exit the procedure room frequently due to the short procedure time; also, operators and assistants pass in and out frequently due to the radiation exposure. The

conditions of interventional procedure room inevitably result in a poor degree of disinfection and cleanliness, as compared to the regular operating room. Current conventional patient contact type procedure has inherently high frequency of infection that can result in higher morbidity and mortality, hence, paradigm change is required to minimize the risk of infection and related complication [6].

4) The procedure relies on the experience and skill of the operator

The procedure is performed with the guide wire and catheter of fine diameter, hence, its success depends on the experience and skill of the operator. Despite large variation in success rates and procedure time, pre-training method for the procedure is limited by the target that mainly includes small vessels [7,8].

2. Development potential of robotic vascular interventional procedure

1) It is easy to develop because the robot operation is relatively simple.

The movements involved are simple, since most vascular interventional procedures are mainly composed of insertion and steering of guide wire and catheter; in addition, the device moves only inside the vessels, the range of movement is very limited and less influenced by patients' respiration and movement, so the procedure is possible with only 3~4 degrees of freedom [6,9].

2) It is easy to secure the stability of the procedure.

The devices are soft and move only in the vessels; hence it is easy to secure stability compared to other surgical robots.

3) Because of the physical stress, disease risks, and the radiation exposure, the automatized vascular intervention robot is in demand by interventionists and it could also increase the efficiency and safety of procedures. As the purchase of hospital material and equipment is mainly decided by the demand from operators, its marketability is expectedly increased due to high demand.

KEY TECHNOLOGIES OF VASCULAR INTERVENTION ROBOT [1] [10]

1. Mechanism and control system: The vascular intervention robot usually adopts a master-slave robot system to keep the operators away from the radiation. It also needs systems to control the guide wire and catheter separately. The systems which can use both the 5 F catheter and the 3 French microcatheter simultaneously are now under development.

2. Image integration and navigation: Conventional vascular intervention is performed under 2-dimensional angiographic imaging. Operators have to reconstruct 3-dimensional images according to subjective anatomy-based experience. For safer and more accurate procedure, integrated display of the intervention device and 3-dimensional vascular image are mandatory.

3. Haptic force-feedback: To assure the safety of remote operating systems of the procedure, it is important to have haptic force-feedback transmitted to the operator's hand on real time. So far, haptic technology is not adapted in current commercialized systems.

CURRENT STATUS OF THE VASCULAR INTERVENTIONAL PROCEDURE ROBOTS

The vascular interventional procedure robotic system has progressed from developmental to commercialization stage. However, it is not actively applied to clinical procedures, and the number of products under research is also limited.

The vascular interventional procedure robotic system approved by the US Food and Drug Administration (FDA), Hansen's Magellan Robotic Catheter System has been developed and commercialized [11]. Despite its limitations, this system is already applied in clinical procedures. A recent report indicates its successful use in the Endovascular Aneurysm Repair (EVAR) procedure [12], with only 5 minutes in set-up time and 3 minutes in selection of the left renal artery. In

addition, this system was reportedly used for the treatment of venous disease in collaboration with Da Vinci robotic surgery that is applied worldwide [13]. The End-effector Magellan system is configured with introducer catheter of maximum 9 French diameter and catheter assembly of maximum 6.1 French diameter, with no significant difference in the catheter used for the actual manual interventional procedure. The catheter can bend 180 degrees and is very advantageous in the vessel selection. However, the coverage is very limited since it is > 1 mm, a 3F sized catheter is required in a variety of vascular interventions, in particular hepatic artery intervention. In addition, there are high limitations of use in the surgical field, due to development as a fully automated system and disadvantage of high cost.

VASCULAR INTERVENTION ROBOT DEVELOPMENT IN OUR LABORATORY

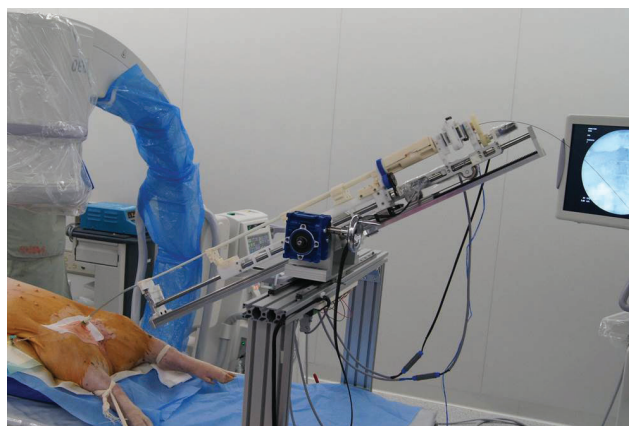


Fig. 5. Our vascular intervention robot system under development. Animal experiment.

We are developing a vascular interventional robotic system which uses the conventional 5-French catheter system that is currently used in the angiography room. The advantage is the possibility of direct application to the field without the need to replace the existing procedure equipment. The final system should be an affordable, reduced sized, semi-automatic system in which only the procedure with high radiation exposure is automatically implemented and the rest is processed manually (Fig.5).

CONCLUSION

Master-slave vascular intervention robot is a new emerging

field in the era of vascular intervention. This approach can drastically reduce radiation exposure by replacing human effort by a robotic system for high radiation exposure procedures. The movement and the trajectory of the robot can be memorized and quantified on the computer so that the procedure can be repeated fast and safely. Further studies to upgrade the current systems and to prove the clinical benefits over the conventional intervention are required.

CONFLICT OF INTEREST

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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