

Use of the Magellan Robotic System for Conventional Transarterial Chemoembolization (cTACE): A 6-Patient Case Series Showing Safety and Technical Success

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Abstract

Robotic endovascular technology is an emerging concept, and is being developed to allow more precise navigation of anatomy in challenging endovascular cases. The Magellan Endovascular System allows either direct or remote steerability of a 2-point articulating robotic platform with the ability to place a conventional microcatheter through the catheter tip. Such flexibility may help to reach an otherwise difficult anatomic location, especially in variant anatomy. To date, this platform has been shown to be technically successful in a small number of different settings. This case series shows another potential platform for such technology and explores the technical use and overall safety in conventional transarterial chemoembolization (cTACE). The study retrospectively assessed 6 patients undergoing selective cTACE. Treatments were performed in a single center by two experienced interventional radiologists. Fluoroscopy time, radiation dose, anatomic target, and adverse events were logged. In spite of a longer than expected average fluoroscopy time, which can be expected for a first-generation technology, the average radiation dose was comparable to literature and technical success was able to be shown in all 6 patients with no adverse events. This technology has wide scope for future use and once overcoming a learning curve, may allow us to avoid repeat procedure attempts thus reducing fluoroscopy time and leading to earlier successful treatment. Providing a platform of interest and usability in the interventional radiology world may also lead to further development of smaller, cheaper, and more widely-accessible devices.

Keywords

- ► TACE
- ► chemoembolization
- ► magellan
- ► robot
- ► robotic
- endovascular
- ► novel

Introduction

Transarterial chemoembolization (TACE) is an established treatment for patients with intermediate stage hepatoma.¹ While there are many patients who can be successfully treated with the use of off-the-shelf catheters and equipment, occasionally variant or difficult vascular anatomy may

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present a challenge. This may require repeat attempts or the treatment may even be abandoned leaving the patient with more limited palliative options.²

Robotic endovascular technology is one approach to navigate the challenges during vascular catheterization. There are different types of robotic technology available allowing assistance during percutaneous CT or fluoroscopic techniques, and there are emerging devices designed for endovascular use.³ These types of devices have been shown to be safe in animal and human models in early data.⁴ The Magellan Robotic System (Hansen Medical) is an endovascular robotic

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device which has been developed to allow precise steering of catheters through potentially difficult anatomy, and was designed to increase the success of otherwise difficult endovascular cases. It has been used in different settings including aortic stent graft placement (both branched and fenestrated aortic repair), carotid stenting, crossing tortuous iliofemoral arteries, selecting tortuous aortic arch vessels, and in uterine fibroid embolization.⁵

The Magellan Robotic System consists of a robotic arm mounted on to the end of the angiography table. A 6-French, 9-French, or 10-French steerable catheter and wire is mounted onto the robotic arm and the robotic arm is controlled by either a bed side control panel or a remote workstation with a control panel that may be located anywhere within or outside the angiography lab (Fig. 1). The catheters have 2 points of flexion where each can be independently steered in all directions. The proximal flexion point is able to be steered to 90 degrees in all directions and the distal flexion point near the tip has the ability to form a 180 degree "J loop shape." The combination of these flexion points allows comprehensive 3-dimensional catheter steerability. In addition the catheter can be advanced or retracted and the wire can be rotated, advanced, or retracted: when both are used in unison, this allows full robotic control of the catheter/wire combination. A standard microcatheter is able to be manually placed within the lumen of the robotic catheter to allow superselective treatment (e.g., selective TACE or other embolization).

The aim of this retrospective review is to show the successful use of this device in navigating hepatic arterial anatomy in conventional TACE, in a bid to add to data showing technical feasibility of this early generation device.

Material and Methods

In 2013, the Magellan Robotic System was installed at our institution. The use of this device was in compliance with local institutional guidelines, and all patients included in

this manuscript were included as per our local institutional Human Research and Ethics guidelines, which included consent for the use of novel technology.

This review covered 6 patients who underwent conventional TACE (cTACE) between 2013 and 2016. Inclusion criteria was any patient with hepatoma requiring cTACE, between 18 and 99 years old, any gender, where anatomy on CT was deemed appropriate for robotic intervention and who consented to the use of the Magellan Vascular robot. All cases were performed with intravenous conscious sedation (midazolam and fentanyl). With sterile preparation and draping of the right groin, using 10 mL (1%) lidocaine to the skin, the right common femoral artery was accessed and a 6-French standard vascular sheath inserted (Terumo). The Magellan Robotic system was then used with a 6-French robotic catheter. The robotic catheter was advanced through the sheath and then robotically controlled to catheterize the hepatic artery, followed by super selection with a microcatheter within the robotic catheter to the tumor location (see **Table 1** for details on catheter locations).

Conventional TACE treatments were performed by mixing a combination of 10 mL lipiodol (Guerbet), 15 mg mitomycin (Teva Pharmaceuticals), and 50 mg cisplatin (Accord Healthcare) for intra-arterial use made to a volume of 50 mL. In addition, all patients received a standard premedication for TACE consisting of cefazolin 1 g intravenous (Sandoz), ondansetron 8 mg intravenous (Accord Healthcare), acetaminophen 1 g oral (GlaxoSmithKline), diclofenac 50 mg oral (Apotex), and oxycontin 10 mg oral sustained release (Purduepharma).

After intra-arterial administration of medications, the arteriotomy was closed with either a femoseal or angioseal vascular closure device (Terumo).

The primary endpoint for this review was technical success, defined as successfully reaching the intended arterial endpoint and administration of chemotherapeutic agent. Secondary endpoint was the presence of complications related to technology or procedure.

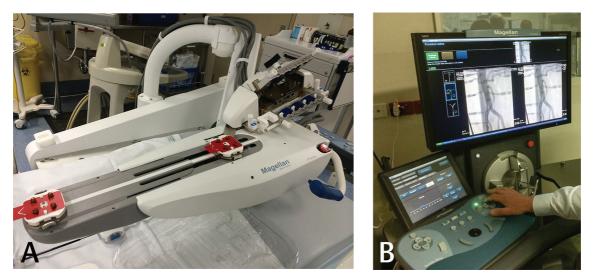


Fig. 1 (A) The Magellan system in place on a Siemens Artis Q Biplane Angiography system and (B) the optional remote control system in the angiography control room.

Results

There were 6 patients included in this cohort, 3 males and 3 females, with average age of 70 years (range 58–84).

- Table 1 shows the demographics of each patient, including the artery superselected to administer the chemotherapy. The average fluoroscopy time was 47.8 minutes, and the average radiation dose to the patient (measured in dose area product [DAP]) was 267.3 Gy.cm².

► Fig. 2 shows the appearance of the catheter during angiography in the hepatic artery. Navigation of the left hepatic artery is shown in ► Fig. 3, while treatment via a replaced right hepatic artery is shown in ► Fig. 4. ► Fig. 5A shows ostial coeliac axis plaque in a patient which was negotiated with the robotic device successfully (► Fig. 5B).

Technical success was achieved in all 6 of the patients in reaching the intended artery for medication administration. Treatment success was also achieved in all patients including tumor staining and absent enhancement at the conclusion.

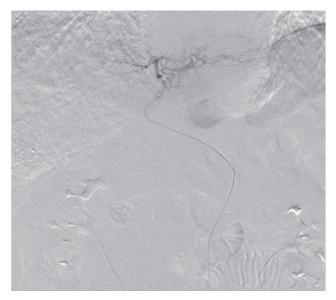


Fig. 3 The robotic catheter is taken to a peripheral branch in the left lobe to allow selective cTACE.

Tal	ble	1	Patient	demogra	ohics
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Age (y)	Gender	Dose (Gy.cm ²)	Fluoroscopy time (min)	Technical success	Complication	Artery selected to administer chemoembolization
62	Male	253	31.3	Yes	No	Left hepatic
58	Male	424	30.5	Yes	No	Right anterior and right posterior hepatic
71	Male	210	35.2	Yes	No	Left hepatic
83	Female	354	52.1	Yes	No	Right posterior hepatic and left hepatic
60	Female	165	83.5	Yes	No	Right posterior hepatic and left hepatic
84	Female	197	54.3	Yes	No	Right hepatic

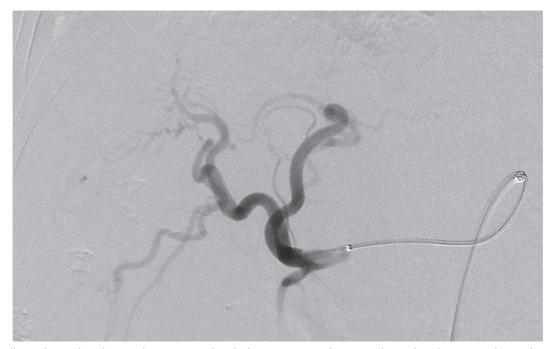


Fig. 2 Magellan endovascular robotic catheter navigated to the hepatic artery and angiography used to plan microcatheter advancement.

There were no complications demonstrated, specifically there were no cases of intimal injury in the coeliac axis or hepatic artery, and no access site complications.

Discussion

This short case series offers another platform for the use of emerging robotic endovascular technology to add to the current literature available in other endovascular models. In our 6 patients, we achieved a rate of 100% technical success. To the authors' knowledge, robotic technology has not been shown in the conventional TACE model in prior literature.

There were no major or minor endovascular complications in our cohort, which supports overall device safety.^{4,5}

The scope for this type of technology is nearly endless and may be contributed to a very rigid platform for navigating large and mid-sized vessels, with still the flexibility to navigate small and tumor-related vessels in the periphery whilst also allowing fine steerability and the ability to change

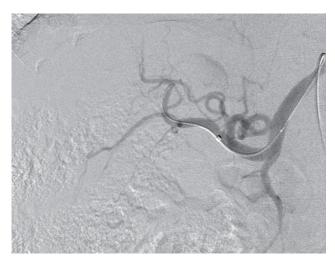


Fig. 4 Navigating a replaced right hepatic artery off the superior mesenteric artery with microcatheter stability to provide downstream selective cTACE.

catheter shape when desired. Diagnostic catheters do not have the advantage of all of these characteristics in a single catheter and the stability may not rival the robotic device. There is also the ability to navigate this remotely and while not used in our series, the technology may allow an experienced proceduralist off-site to provide assistance in the manner of other robotic surgical devices.⁶ The ability to overcome challenges and thus avoid repeated treatment attempts may also lead to earlier successful treatment.

While the average fluoroscopy time of 47.8 minutes is high, this reflects a learning curve of operator experience and also a first-generation technology. The two experienced operators noted the device easy to use once set up. In spite of the longer fluoroscopy time, the average patient radiation dose of 267.3 Gy.cm² (range 165–424 Gy.cm²) is comparable to that in the literature, which likely reflects the influence of low-dose screening where the number of higher-dose angiographic runs are less likely to have changed. In the long-term, there is the potential to reduce dose to both the patient and to the operator by preventing long cases or repeat angiographic attempts for otherwise difficult anatomy, however, dose and time comparisons in such a heterogeneous treatment cohort was not the primary aim of this case series and remains a challenge to measure even across standard TACE treatments between operators and institutions.

The use of emerging robotic technology such as the Magellan Robotic System in the TACE model is safe and feasible with technical success in our cohort, and offers many potential advantages in terms of precise catheter maneuverability. It has the potential in the future to reduce repeat procedure attempts which can have flow-on effects in providing earlier treatment success and reducing fluoroscopy time, which may be further investigated.

Conflicts of Interest None declared.

Acknowledgements None.

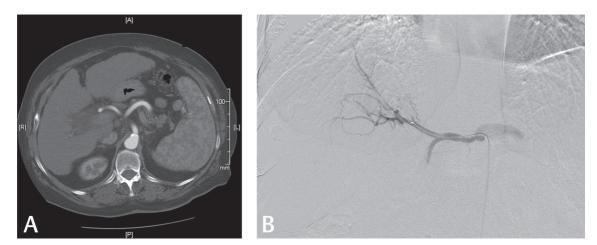


Fig. 5 Ostial coeliac axis plaque (A) was able to be navigated using the robotic technology and (B) catheter situated successfully in the hepatic artery.

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