The use of robotic endovascular catheters in the facilitation of transcatheter aortic valve implantation

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Received 6 June 2013; received in revised form 17 September 2013; accepted 26 September 2013

Abstract

OBJECTIVES: The use of transcatheter aortic valve implantation (TAVI) is rapidly increasing with advances in technology and improved clinical outcomes. Adoption of robotic catheter technologies could have a role in TAVI, in different stages of the procedure, to improve endovascular tool manipulation and potentially reduce the risk of cerebral embolization. The aim was to determine whether there are advantages in using a robotic catheter for TAVI in the initial stages of the procedure; aortic arch navigation and valve crossing.

METHODS: A silicone in vitro model of the aorta and stenotic aortic valve was developed. Fifteen operators performed the fluoroscopy-guided simulation using manual and robotic techniques. Performance metrics—time and vessel wall contact (wall-hits) were compared (Wilcoxon’s signed-rank test).

RESULTS: Overall, the time taken for robotic arch navigation was increased (3.09 min interquartile range (1.24–6.29) vs 1.21 min (0.15–4.42); P = 0.03). Contact with the aortic arch wall, however, significantly decreased using the robotic catheter: wall-hits 1 (0–5) vs 6 (2–22), P < 0.01. For valve crossing, there was no significant increase in time and wall-hits when using the robotic technology.

CONCLUSIONS: Use of robotic catheter technology is feasible in the initial stages of TAVI. Although it takes longer, robotic navigation reduces contact with the aortic arch wall, potentially reducing the embolic risk during endovascular manipulation. Using a robotic catheter is possible without increasing the number of wall-hits during valve crossing. This may provide a stable platform for wire positioning in the ventricle. With improvements in technology, perhaps allowing valve deployment, the stability and accuracy of the robotic arm may further improve performance.

Keywords: Transcatheter aortic valve implantation • Catheter • Navigation • Embolization • Stroke • Robotic transcatheter aortic valve implantation

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a new approach to heart valve replacement. It has enabled treatment of patients with severe aortic stenosis, not suitable for surgical intervention. Patients unable to undergo open heart surgery can be treated with TAVI, greatly improving their quality of life [1, 2]. Open heart surgery has a low complication rate and good long-term quality-of-life outcomes in patients with acceptable risks for surgery [3, 4]. A recent study, however, showed that TAVI has also been performed in lower surgical risk patients with a decrease in mortality and no difference in transient ischaemic attack (TIA) and stroke when compared with open heart surgery [5].

A significant problem with TAVI involves macro- and microembolization, which occurs in as many as 10% of all patients undergoing the procedure [6]. This may result in stroke and significant cognitive impairment [7]. A recent randomized trial of TAVI vs open surgery demonstrated a reduced early mortality rate but an increased risk of stroke and vascular complications, and a doubled rate of all neurological events [8]. The majority of cerebrovascular complications after TAVI are detected on computed tomography (CT) scanning between 0 and 7 days after the procedure indicating direct procedural causative mechanism of embolization [9]. The recently published PARTNER trial reporting on the 2-year clinical outcomes post-TAVI demonstrates comparable results to open aortic valve replacement with no difference in stroke rates and significantly more overall stroke and TIA events in the TAVI group (11.2% for TAVI vs 6.5% for open surgery, P = 0.05) [10].

One potential way of reducing embolic load in transfemoral TAVI would be by minimizing instrumentation in the aortic arch during wire and catheter positioning, reducing the number of catheter changes and increasing the stability of catheters during valve crossing [6, 8, 11–15]. The purpose of this study was to determine the role of robotic endovascular catheter technology during the initial stages of TAVI.
METHODS

Robotic catheter system

The Magellan™ System (Hansen Medical, Mountain View, CA, USA) is a ‘master-slave’ endovascular robotic platform, which controls a catheter system via a remote workstation. The robotic catheter consists of a 6-Fr leader catheter with a 180° multidirectional articulation, and a 9.5-Fr sheath with an additional 90° multidirectional articulation. Both leader and sheath components are steerable and controlled by the operator from a remote robotic workstation, which displays the relevant fluoroscopic imaging along with a superimposed virtual image of the guide catheter with vectors for planar orientation and navigation. The system offers full rotational ability and a leader workspace defined by a bend of up to 180° and a 21 cm extension, and more importantly independent torque control at the tip without catheter shaft rotation. Furthermore, a robotic wire manipulator allows remote insertion, rotation and retraction of conventional 0.018 and 0.035 hydrophilic wires. The robotic catheter can be used with a variety of existing diagnostic and therapeutic percutaneous devices inserted through the sheath lumen. An auto-retract function enables passive retraction of the catheter into a neutral position and the catheter can be withdrawn while keeping the wire in a stable position.

In vitro model

An experimental model was designed specifically for simulation of the TAVI procedure in vitro. A CT-based anthropomorphic silicone phantom representing a type I aortic arch (Elastrat, Switzerland) was used. The arch was modified by creating a stenosed aortic valve opening (0.6 cm²) in accordance with the National Institute for Health and Clinical Excellence (NICE) guidelines for the use of TAVI in cases where surgical valve replacement is not possible, due to patient comorbidities [16]. The left cardiac ventricle was modifi ed by creating a stenosed aortic valve and left ventricle. Each operator was asked to perform the TAVI procedure using robotic and conventional techniques, in a randomized order. No trial runs were performed and all operators were novice in the use of the robotic system.

Participants

Fifteen operators were invited to participate in the study and stratifi ed into three groups depending on their previous endovascular experience [17]:

(i) Experts > 100 endovascular procedures performed (n = 6).

(ii) Intermediate 20–100 endovascular procedures performed (n = 3).

(iii) Novices no previous endovascular experience (n = 6).

All participants were consented for participation in the study and briefed on the protocol using standardized didactic teaching material; a presentation summarizing the key steps of both conventional and robotic procedures was provided. Aortic arch navigation and valve crossing were the two steps of interest. All operators were asked about their previous endovascular experience. Following the brief, they were asked to perform a single conventional and single robotic simulation in a random order. No trial runs were performed and all operators were novice in the use of the robotic system.

Data analysis

Arch navigation was defined as wire and catheter advancement from the descending aorta at a level marked by the most proximal portion of the left ventricle (Fig. 1&2) to 2 cm proximal to the aortic valve. Valve crossing was defi ned as advancement of the wire and catheter from 2 cm proximal to the aortic valve, to 2 cm into the left ventricle. Each operator was asked to perform theprocedure using robotic and conventional techniques, in a randomized order.

All videos were anonymized and assigned a random, computer-generated code. Data collected included time to complete the two steps, from continuous fl uoroscopy screen capture. Video recordings were analysed twice by a single assessor (Radoslaw A. Rippel) to count the number of wall-hits observed during arch...
navigation and valve crossing. Wall-hits have been previously validated as an assessment method [18, 19] and were defined as a purposeful forward movement of the catheter or wire tip resulting in contact with the vessel wall as seen on the two-dimensional (2D) fluoroscopy screen. Measurement was consistent for all videos and results were analysed looking for differences in performance between conventional and robotic techniques as well as between experience groups. Analysis of the number of wall-hits was performed twice for each sample to check for inter-test reliability using Cronbach’s alpha test.

All expert operators were asked to fill in a face validity questionnaire to grade the realism of the in vitro model. A Likert scale was used to grade the responses from 1 = strongly disagree to 5 = strongly agree. The questionnaire was designed to compare the in vivo procedure to the in vitro set-up in terms of anatomy, quality of imaging and visualization, type of instruments provided, haptic feedback, response of the model and the overall realism of the simulation.

Data were analysed using SPSS 20.0 and Microsoft Excel 2007. Median values were used to compare results between the sample groups. The Wilcoxon signed-ranked test was used to compare robotic to conventional performance for each operator. The Kruskal-Wallis test was used to analyze differences between groups of experience with post hoc analyses using the Mann-Whitney U-test. In addition, Spearman’s test was used to assess correlations between measured factors (time, wall-hits). The difference was accepted as significant if the P-value was <0.05.

RESULTS

Face validity

Overall, experts rated the simulation 3.5 of 5 (3.5/5). Mean scores included: 4/5 (interquartile range (IQR) 4–4) when comparing the model to the real procedure, 3.83/5 (3–5) for the anatomy and imaging quality, 3.5/5 (2–4) for appropriateness of instruments provided, 3/5 (2–4) for procedure realism and 3.33/5 (2–4) for haptics of the model.

Inter-test reliability

Inter-test reliability was excellent for both arch navigation (α = 0.980) and valve crossing (α = 1.000).

Arch navigation

Overall, the time taken was significantly higher with the use of the robotic catheter (3.09 min IQR (1.24–6.29) vs 1.21 (0.15–4.42), P = 0.03). The difference was significant for the expert group (2.54 (1.24–4.03) vs 0.23 (0.15–2.04), P = 0.03). Novice and intermediate groups also took longer to complete the task using the robotic technique; however, the differences were not statistically significant (P > 0.05).

There was a reduction in the number of wall-hits when the robotic system was used (Fig. 3). Analysis of data for all operators showed a median of one wall-hit using the robot, compared with six wall-hits in the conventional approach during arch navigation (1 (0–5) vs 6 (2–22), P < 0.01). During subgroup analysis, the expert (0.5 (0–5) vs 5 (2–11), P = 0.09) and intermediate group (1 (0–2) vs 5 (5–6), P = 0.10) showed a reduction in the number of wall-hits when the robot was used; however, the results were not significant. The novice group demonstrated a significant reduction in the number of wall-hits (2.50 (0–5) vs 7 (3–22), P = 0.046) using robotic technology.

Results for arch navigation were also compared between the groups of experience. There was a significant difference in time taken for conventional arch navigation between groups (Table 1): 2.79 (1.21–4.42) vs 1.16 (0.51–1.45) min, (P = 0.05) when comparing the novice and intermediate groups, and 2.79 (1.21–4.42) vs 0.23 (0.15–2.04), (P < 0.01) when comparing novices vs experts.

Table 1: Comparison of results between experience groups for time (min) and number of wall-hits (median). The Kruskal-Wallis test was used

<table>
<thead>
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<th>Novice</th>
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<td>Wall-hits (arch)</td>
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<td>Rob</td>
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<td>Time taken (valve)</td>
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<td>Conv</td>
<td>6.65</td>
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<td>Rob</td>
<td>5.61</td>
<td>4.20</td>
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<td>Wall-hits (valve)</td>
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<td>Conv</td>
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<td>Rob</td>
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Conv: conventional; Rob: robotic; time (min).
*Significant difference for novice vs intermediate and novice vs experts, no difference intermediate vs experts.
There was no difference between intermediate and expert groups (1.16 (0.51–1.45) vs 0.23 (0.15–2.04), P = 0.17). Arch navigation using the robotic catheter demonstrated a non-significant step-wise decrease in the time taken with increasing experience (Fig. 3).

There was no significant difference across the groups of experience in both conventional and robotic arch navigation in terms of wall-hits. Although this did not reach statistical significance (P > 0.05) (Table 1), there was a trend showing a reduction in the number of wall-hits with increasing experience. The trend was observed for both conventional and robotic techniques (Fig. 3).

**Valve crossing**

No differences were seen between the robotic and conventional technique for time 4.20 (1.05–32.35) vs 2.51 (0.23–11.05); (P = 0.36) and wall-hits 12 (3–144) vs 18 (1–91); (P = 0.71). Results are graphically presented in Fig. 2. Experts crossed the valve faster than novices using the conventional technique (1.33 (0.23–6.21) vs 6.65 (2.20–10.25), P = 0.041). There were no significant differences between groups of experience in terms of wall-hits and time using the robotic technology (Table 1 and Fig. 3).

**DISCUSSION**

The necessity for further investigation of the source of embolization and the introduction of methods to minimize embolic risk has been emphasized previously [20], and retrograde arch navigation has been identified as one of the causative mechanisms in TAVI [15]. This study focuses on arch navigation and valve crossing as steps which could potentially be made safer with the use of the robotic technology. A number of preclinical studies have shown robotic cannulation to be an effective technique both in the visceral segment and also for the arch vessels by reducing procedure and fluoroscopy times, unnecessary catheter movements and vessel wall contact [18, 21, 22]. Avoiding contact with the aortic wall during the TAVI procedure, especially during the initial stages of the procedure, may be important for reducing the embolic load resulting from endovascular manipulation [23]. Reports suggest as much as 37% of all embolization in TAVI occurs during

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**Figure 3:** Bar charts showing results for both arch navigation and aortic valve crossing. The bars represent median results. The whisker plot indicates IQR. Significant differences between conventional and robotic techniques are marked with asterisk. Values marked with ‘x’ are outliers. All P-values have been obtained using the Wilcoxon signed-rank test.
wire and catheter manipulation of the arch and valve [24]. If mini-
mized, it could lead to a significant reduction in the rate of all
cerebrovascular complications.

Arch navigation

This study demonstrated that time taken for aortic arch navigation
is increased when the robot is used. This may be partially due to
the learning curve with the use of a robotic catheter. The majority
of the operators had no previous experience of using the robot
and have not performed TAVI before. It is worth noting that the
procedure time has been shown not to increase risk of emboliza-
tion in TAVI [6] in contrast to carotid intervention, which has a
time-dependent embolization risk.

We have demonstrated a significant reduction in the number of
wall-hits during arch navigation. Wall-hits may be a surrogate
marker for embolic potential; however, with a 3-fold decrease in
wall-hits to the arch, the robotic catheter presents an attractive
platform and significant technological improvement, which may
translate into a measurable reduction in embolization and stroke.
Importantly, experienced operators demonstrated reduced wall-hit rates by 5-fold and performed a near non-traumatic arch
navigation (median 0.5).

Valve crossing

All measures of performance during valve crossing were not sig-
nificantly different between conventional and robotic techniques.
Most of the operators found it challenging to locate the aortic
valve and advance through the valve opening. The absence of any
significant differences in performance metrics in this phase of the
procedure between groups of experience using the robotic cath-
ether may suggest that the robotic catheter presents a new learning
curve even for experts, and therefore eliminates any advantage
they may have had over novices. Importantly, however, there was
no increase in the number of wall-hits.

One further advantage of a robotic platform for the later stages
of TAVI relates to the reduced radiation dose to the operators and
staff in the angiology suite. For robotic navigation, the radiation
dose to operators was zero, as the robotic workstation is located
outside the fluoroscopy suite and away from the X-ray source.
Although there is no literature available at present, the operator
sits outside the operating theatre, using the workstation, where
she/he is not exposed to the radiation source. No additional risk
of using the robotic system when compared with the conventional
endovascular procedure has been identified so far.

This study has a number of limitations. The stages of the pro-
cedure did not perfectly reflect clinical TAVI workflow. A step that
was intentionally omitted from this simulation was the placement
of a pacing wire intraluminally, normally performed at the begin-
ning of the procedure. In principle, the robotic catheter could be
used for this step; however, the potential benefit would not be
dissimilar from the steps that have been investigated and pre-
sented in this paper. The placement of a stiff wire in the ventricle
prior to valve delivery could be facilitated by the use of a robotic
catheter system. The ability of the robotic catheter to form a
stable curved shape in the ventricle may reduce the need for cat-
ther exchange required for placement of a stiff wire to reduce the
risk of ventricular perforation, which is a recognized complication
of the procedure. Valvuloplasty and valve graft delivery were also

Figure 4: The silicone in vitro model.

omitted as, in its present form, the diameter of the robotic cath-
ether cannot accommodate such devices; however, this study
sought to identify potential benefits of the robotic system as a
navigation tool to aid cannulation and valve crossing; the evalu-
ation of a robotic catheter to facilitate graft delivery was therefore
beyond the scope of this investigation. In addition, the phantom
was limited, as it did not represent the full intravascular path via a
transfemoral access route (Fig. 4); the addition of the abdominal
aorta with iliac arteries would allow for more direct representation
of the intravascular path via the transfemoral route. Nonetheless,
the face validity questionnaire completed by experts showed
good correlation with their clinical experience. Finally, our per-
formance measures, time taken and number of wall-hits are
merely surrogate markers of performance and embolization, and
further investigation is warranted to identify more accurate
markers of direct procedural assessment.

Future directions

It is clear that the 2D fluoroscopic images used during TAVI are
limiting, as they do not provide precise anatomical orientation
which may prevent accurate catheter positioning at the opening
of the valve and non-traumatic passage into the ventricle.
Clinically, some operators utilize transoesophageal echocardiog-
raphy in addition to fluoroscopic views. If the potential of the
robotic system is to be fully utilized, more advanced three-
dimensional (3D) imaging modalities, which would enable true
real-time 3D navigation, need to be developed and fully inte-
grated. Such technology may facilitate direct visualization of the
valvular orifice via a trajectory view. Development of advanced
navigation systems for TAVI utilizing echocardiography, magnetic
resonance imaging, CT and electromagnetic technologies are
already in progress and could prove a valuable addition to the
robotic approach. The use of 3D transoesophageal echo may also
have a role and potential for further improvement of performance
during TAVI. Modifications to the robotic platform are also neces-
sary if endovascular robotic technology is to be adopted for TAVI
use. The robotic catheter could be modified to deliver the balloon
and valve delivery system directly, so that multiple catheter
exchanges could be avoided and the robotic catheter could
provide a stable platform for device delivery. Further research and
device development is therefore required to assess the full potential of robotic technology in TAVI.

CONCLUSIONS

The use of robotic catheters is feasible in the initial stages of TAVI. The time taken for aortic arch navigation is prolonged; however, this was associated with a significant reduction in vessel wall contact during endovascular manipulation with the use of the robot. The active manoeuvrability and control of the robotic catheter tip may potentially reduce embolization and stroke rates in TAVI. The coaxial catheter system may also offer a stable platform for valve crossing and subsequent placement of stiff wires into the ventricle, and, if technology allows, for valve deployment. With further research and development into device delivery and real-time image integration, TAVI may be possible using a wholly robotic endovascular approach with significant advantages.

ACKNOWLEDGEMENTS

Many thanks to the participants in the study from the Imperial Vascular Unit, Department of Cardiology and the Department of Interventional Radiology.

Funding

The Royal College of Surgeons of England supported Radoslaw Rippel during the research period with an Intercalated Bachelor of Science Degree in Surgery or Surgical Related Area Award, 2011/12. This study was partly funded by Hansen Medical, Mountain View, California as well as Imperial College Healthcare Trust, and the National Institute for Health Research (NIHR) through the Comprehensive Biomedical Research Centre.

Conflict of interest: Hansen Medical has provided institutional level funding to Imperial College, and Nicholas J. Cheshire, Mohamad Hamady, Celia V. Riga and Colin D. Bicknell have received payment for consultation and educational purposes from the company.

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