Advanced Catheter Technology: Is This the Answer to Overcoming the Long Learning Curve in Complex Endovascular Procedures

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Abstract
Introduction: Advanced endovascular procedures require a high degree of skill with a long learning curve. We aimed to identify differential increases in endovascular skill acquisition in novices using conventional (CC), manually steerable (MSC) and robotic endovascular catheters (RC).

Materials/methods: 10 novices cannulated all vessels within a CT-reconstructed pulsatile-flow arch phantom in the Simulated Endovascular Suite. Subjects were randomly assigned to conventional/manually-steerable/robotic techniques as the first procedure undertaken. The operators repeated the task weekly for 5 weeks. Quantitative (cannulation times, wire/catheter-tip movements, vessel wall hits) and qualitative metrics (validated rating scale (IC3ST)) were compared.

Results: Subjects exhibited statistically significant differences when comparing initial to final performance for total procedure times and catheter-tip movements with all catheter types. Sequential non-parametric comparisons identified learning curve plateau levels at weeks 2 or 3 (RCs, MSCs), and at week 4 (CCs) for the majority of metrics. There were significantly fewer catheter-tip movements using advanced catheter technology after training (Week 5: CC 74 (IQR 59–89) versus MSC 62 (44–81); p = 0.028, and RC 33 (28–44); p = 0.012). RCs virtually eliminated wall hits at the arch (CC 29 (28–76) versus RC 8 (6–9); p = 0.005) and produced significantly higher overall performance scores (p < 0.02).

Conclusion: Advanced endovascular catheters, although more intricate, do not seem to take longer to master and in some areas offer clear advantages with regards to positional control, at a faster rate. RCs seem to be the most intuitive and advanced skill acquisition occurs with minimal training. Robotic endovascular technology may have a significantly shorter path to...
Endovascular intervention is rapidly evolving, allowing more complex aortic pathology to be treated via a minimally invasive route. Guide wire, catheter and sheath use constitute the foundation of endovascular therapy, both technically and conceptually. Despite the exponential advances in equipment, devices and techniques, patient-specific anatomical factors leading to difficult catheter manipulation require considerable technical skill. As case complexity increases and endovascular intervention becomes more ambitious, the mastering of endovascular skills can be challenging.

A variety of advanced endovascular catheters have been developed for use in minimally invasive cardiac intervention in an attempt to overcome some of the limitations of conventional endovascular catheters (CCs). These systems have not been widely adopted in vascular surgery and peripheral arterial interventions. The impact of such technology on the skill acquisition for endovascular procedures to date has not been explored. This study aims to investigate the role of advanced manually steerable catheter (MSC) and robotic catheter (RC) in endovascular skill acquisition of novice subjects.

**Materials/Methods**

Ten novice subjects (medical students) with no prior endovascular training were recruited and consented to participate in the study; ethical approval was not required. A silicon-based, transparent, computed tomography (CT)-reconstructed anthropomorphic phantom representing a type I aortic arch was used (Elastrat Sàrl, Geneva, Switzerland). The phantom was filled with a blood-mimicking water–glycerol mixture (60:40 by volume concentration) and circulated using a pulsatile blood pump providing physiologically realistic blood-flow waveforms. A range of 4-French (Fr) to 5-Fr selective catheters and appropriate endovascular guidewires, commonly used in arch vessel cannulation procedures, were available to all operators.

**MSC technology**

A 5.5-Fr VascoCath® MSC device (PolyDiagnost GmbH, Germany), 60 cm in length, was used in combination with a 0.018” guide wire. The operator controls the amount of curvature at the catheter tip via a handle that permits locking at the desired shape (Fig. 1a). It has two working channels and allows for a deflection of up to 180°, via pull wires (Fig. 1b). Proximal to this, there is a 35-mm length portion of the catheter with low rigidity, acting as an additional bend.

**RC technology**

The Sensei™ System (Hansen Medical, Mountain View, CA, USA) has been described in previous publications. In brief, it is a remotely steerable electromechanical catheter system controlled via a ‘master–slave’ mechanism. The workstation is remote, located outside the angiography suite and away from the radiation source. The workstation console displays imaging and the catheter tip force sensing feedback data, along with a superimposed virtual image of the guide catheter with vectors for planar orientation and navigation. The operator steers the robotic catheter via a three-dimensional (3D) hand-operated joystick. The RC itself consists of a flexible, multidirectional inner guide (11-Fr outer diameter, 8.5-Fr inner diameter) with a 270° bend radius and 7 degrees of freedom, inside a unidirectional outer guide sheath (14-Fr outer diameter, 11-Fr inner diameter). A remote catheter manipulator (RCM), a robotic arm located at the patients’ bedside, delivers the RC and receives catheter position commands from the workstation.

**Study protocol**

All participants were given an information sheet followed by a standardised didactic teaching session that included
endovascular techniques, apparatus being used, study purpose and assessment metrics. The subject’s understanding of the introductory course was then assessed using a questionnaire. Feedback was provided before progressing to the next stage. Before commencing the study, participants were given a short, practical demonstration of target vessel cannulation and equipment use. They were then allowed to practise cannulating the left subclavian artery (LSA) in the pulsatile aortic arch model. Subjects were then randomly assigned to conventional, manually steerable and robotic techniques as the first procedure undertaken.

Subjects were asked to sequentially cannulate four arch vessels namely the LSA, left common carotid artery (LCCA), right common carotid artery (RCCA) and right subclavian artery (RSA) via the femoral approach. All procedures took place in the Simulated Endovascular Suite (Figs. 2 and 3) and were recorded for video assessment. Each task was repeated weekly over a 5-week period (15 sessions per subject, 150 procedures in total). At the end of the 5-week training programme, video recordings were analysed for quantitative and qualitative metrics. Video footage was blinded and randomised, identifiable only by an internal coding system. Qualitative performance was analysed by two blinded vascular specialists who are experienced in the use of endovascular rating scales and were not involved in the data collection. Subjects were also sent a post-training self-report questionnaire on their overall experience with conventional, manually steerable and robotic endovascular techniques.

Data Collection

Quantitative metrics

Total procedure times and individual target vessel cannulation times were measured using a stopwatch. Times were recorded from the catheter entering the phantom at a fixed point at the descending aorta, and vessel cannulation was deemed satisfactory when the catheter was seen in a stable position over the guide wire and at least 3 cm into the target vessel. In addition, the absolute number of rotational and translational movements at the wire/catheter tip and wall hits during cannulation attempts were recorded in a binary fashion by two independent observers, who were blinded to...
each individual operator and corresponding session. A wall hit was defined as any contact with the vessel wall proximal to the origin of the LCCA and at the carotid vessel ostium.

**Qualitative metrics**

Operator performance was evaluated using the Imperial College Complex Cannulation Scoring tool (IC3ST). The IC3ST was developed based on the established Objective Structured Assessment of Technical Skills (OSATS) scale, and has been previously validated and reliably used for procedure-specific scoring in endovascular skill studies. The scale consists of seven domains, each measured on the five-point Likert scale. Descriptive comments for each technical domain are given at each of these anchoring points. The minimum attainable score is 7, and the maximum is 35; the higher the score, the better the performance.

**Statistical analysis**

Data were analysed with the Statistical Package for the Social Sciences version 18.0 (SPSS, Chicago, IL, USA). Learning curves were assessed using a Friedman (non-parametric repeated-measures analysis of variance) test. Sequential comparisons were made to identify plateau levels for all significant variables. The Wilcoxon signed rank test was used to determine both skill improvement from the first to fifth session and differences between CC, MSC and RC. All tests were two-tailed and considered significant for \( p < 0.05 \). Inter-observer reliability for blinded assessors was evaluated by determining a value for Cronbach’s alpha. It is suggested that for research purposes, a reliability coefficient of 0.7–0.8 is sufficient, and for a high-stakes assessment, this coefficient should be 0.9.

**Results**

**Skill acquisition**

All study participants completed the 5-week training programme, with the exception of one who failed to complete the fifth and final session using MSCs. Adequate inter-observer reliability for blinded assessors was achieved for all metrics: total number of procedure movements (Cronbach’s alpha = 0.99), wall hits (0.75) and IC3ST scores (0.87). Subjects exhibited statistically significant differences when comparing initial to final performance (week 1 vs. week 5) for total procedure times and catheter-tip movements. The 5-week training programme had no effect on wall hits for CCs and RCs, and performance scores with robotic catheterisation. Sequential non-parametric comparisons identified a learning curve plateau level at week 3 for all metrics when using the MSC. Using the RC, a plateau was reached at week 3 for total procedure times and IC3ST scores; an earlier plateau at week 2 was seen for catheter-tip movements and wall hits. For CCs, the plateau level was identified at week 3 for total number of movements and week 4 for total procedure times; no plateau was reached for total number of vessel wall hits and performance scores, which continued to improve throughout the training programme. **Table 1** summarises the results for weeks 1 and 5, including learning curve plateau levels for the three different catheter types.

**Comparison between catheter types**

Direct comparison of each catheter type for median procedure times indicated that conventional catheterisation was significantly faster for weeks 1, 4 and 5 when compared with MSC and RC (**Graph 1**). Subjects, however, made significantly fewer catheter-tip movements when using MSCs at weeks 4 and 5, and RCs at weeks 1, 2, 4 and 5 compared with conventional techniques (week 5: CC 74 innovative time range (IQR) (59–89) vs. MSC 62 (44–81); \( p = 0.028 \) and RC 33 (28–44); \( p = 0.012 \) (**Graph 2**). Similarly, there was a significant reduction in the number of vessel wall hits at week 3 and week 4 for MSC. The robotic system virtually eliminated wall hits at the arch (CC 29 (28–76) vs. RC 8 (6–9); \( p = 0.005 \) (**Graph 3**).

RCs resulted in significantly higher performance scores on the IC3ST scale (\( p < 0.02 \)). There was no significant difference in IC3ST scores between CCs and MSCs at any time point. Subcategory analysis of the IC3ST scores, however, suggests enhanced performance in the ‘areas of

**Table 1** Results for all metrics for weeks 1 and 5, including learning curve plateau levels for conventional (CC), manually steerable (MSC) and robotic catheters are summarised in the table below.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Catheter Type</th>
<th>Week 1 median (IQR)</th>
<th>Week 5 median (IQR)</th>
<th>Week 1 vs. Week 5 (p value)</th>
<th>Plateau</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time (min)</td>
<td>CC</td>
<td>64 (4.6–10.1)</td>
<td>4.2 (3.1–6.1)</td>
<td>0.022</td>
<td>Week 4</td>
</tr>
<tr>
<td></td>
<td>MSC</td>
<td>15.5 (10.5–19.8)</td>
<td>6.3 (5.4–7.1)</td>
<td>0.007</td>
<td>Week 3</td>
</tr>
<tr>
<td></td>
<td>RC</td>
<td>12.4 (10.1–13.1)</td>
<td>5.3 (4.3–9.2)</td>
<td>0.005</td>
<td>Week 3</td>
</tr>
<tr>
<td>Movements</td>
<td>CC</td>
<td>205 (165–282)</td>
<td>74 (59–89)</td>
<td>0.005</td>
<td>Week 3</td>
</tr>
<tr>
<td></td>
<td>MSC</td>
<td>210 (129–320)</td>
<td>62 (44–81)</td>
<td>0.005</td>
<td>Week 3</td>
</tr>
<tr>
<td></td>
<td>RC</td>
<td>124 (81–137)</td>
<td>33 (28–44)</td>
<td>0.005</td>
<td>Week 2</td>
</tr>
<tr>
<td>Wall hits</td>
<td>CC</td>
<td>47 (32–107)</td>
<td>29 (28–75)</td>
<td>0.135</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>MSC</td>
<td>61 (40–92)</td>
<td>40 (32–25)</td>
<td>0.015</td>
<td>Week 3</td>
</tr>
<tr>
<td></td>
<td>RC</td>
<td>5 (4–7)</td>
<td>7 (5–10)</td>
<td>0.200</td>
<td>Week 2</td>
</tr>
<tr>
<td>IC3ST</td>
<td>CC</td>
<td>20/35 (14/35–22/35)</td>
<td>26/35 (19/35–27/35)</td>
<td>0.036</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>MSC</td>
<td>16/35 (10/35–20/35)</td>
<td>25/35 (23/35–26/35)</td>
<td>0.007</td>
<td>Week 3</td>
</tr>
<tr>
<td></td>
<td>RC</td>
<td>29/35 (25/35–32/35)</td>
<td>30/35 (29/35–32/35)</td>
<td>0.310</td>
<td>Week 3</td>
</tr>
</tbody>
</table>
significant embolic potential' domain at weeks 3 and 4 for MSCs in comparison with CCs ($p < 0.046$) (Graph 4).

Self-report questionnaires

Seven out of 10 participants preferred MSCs to CCs. When asked what the major limitation with MSCs was, 4/10 stated that "the control handle takes time to get used to," 7/10 stated "it is difficult to torque" and 4/10 said "it lacks flexibility." When asked what they would improve about the MSC device, 7/10 wished it was "bidirectional"; 8/10 participants scored the robotic system at 3 on a 3-point scale (indicating that the system was easy to learn on and steer, and was intuitive and responsive to operator commands). By contrast, 9/10 operators scored the conventional system at 2, on the same scale. Overall, participants preferred the robotic system and felt that it significantly enhanced their performance as a whole.

Discussion

As seen with other fields of minimally invasive surgery, the level of procedural difficulty in endovascular interventions has increased in recent years, as its applicability extends to

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**Graph 1**  Bar chart representing procedure times (minutes) with conventional (CC), manually steerable (MSC) and robotic catheters (RC) throughout the 5-week training programme. Median procedure times are shown on the y-axis. The error bars represent the interquartile ranges (Wilcoxon signed rank test).

**Graph 2**  Bar chart representing the number of movements at the catheter tip during cannulation attempts with conventional (CC), manually steerable (MSC) and robotic catheters (RC) throughout the 5-week training programme. Median values are shown on the y-axis. The error bars represent the interquartile ranges (Wilcoxon signed rank test).
a more complex patient cohort. Catheter-based intervention requires a high degree of skill while manipulating intravascular devices often using counterintuitive hand movements. Consequently, trainees are challenged by the prolonged learning curves associated with mastering complex techniques and the acquisition of essential generic skills. This is highlighted by the extensive caseload, and the long mentoring and proctoring process required in order meet credentialing guidelines for endovascular procedures.

A further obstacle faced by the endovascular specialist trainee involves the limitations of current endovascular catheter technology. CCs pose a number of technical constraints: they have limited distal shape range, take time to change over and rely heavily on operator skill to manoeuvre the catheter tip and maintain stability at target sites. Difficult and repeated instrumentation may also prove problematic, as it increases the risk of vessel trauma and embolisation; this is particularly pertinent in

Graph 3  Bar chart representing the number of vessel wall hits during cannulation attempts with conventional (CC), manually steerable (MSC) and robotic catheters (RC) throughout the 5-week training programme. Median values are shown on the y-axis. The error bars represent the interquartile ranges (Wilcoxon signed rank test).

Graph 4  Graph representation of the overall IC3ST performance with conventional (CC), manually steerable (MSC) and robotic catheters (RC) throughout the 5-week training programme. The error bars represent the interquartile ranges (Wilcoxon signed rank test).
instrumentation within the aortic arch, which invariably increases the risk of cerebral embolisation and stroke. As such, these procedures are unique in that the risk posed to the patient as a result of the surgeon’s learning curve is significant and immediately apparent. Therefore, there is a pressing need to improve endovascular catheter technology in order to shorten the learning curve and in turn improve patient outcomes. A variety of advanced endovascular catheters have been developed in an attempt to reduce the technical burden to the endovascular specialist and have been widely adopted in transvenous cardiac vascular catheters have been developed in an attempt to justify its widespread use in arch vessel cannulation and aptitude for new skill acquisition.

In our study, quantitative and qualitative metrics improved throughout the 5-week training programme (15 sessions for each operator), indicating that novices progressed through the learning curve with regard to basic endovascular skills. Evidence of improvement in performance is supported by the fact that subjects showed less variability in metrics as they progressed through their training, as demonstrated by a reduction in the IQR. This is an important parameter to look for when evaluating skill acquisition and suggests consistency; the rate of improvement in performance seems to decelerate as the learning curve reaches a plateau.

RCs resulted in significantly superior overall performance scores, with an earlier learning curve plateau. The clear advantages with regard to catheter movements and vessel wall hits observed indicate enhanced economy of movement and navigational accuracy. Although catheter-tip movements and vessel wall hits are surrogate measures for embolic risk, wall hits at the arch are virtually eliminated by the robotic system. This is likely to result from the greater range of motion that can be achieved with the RC and the increased 3D control at the catheter tip. Overall IC3ST performance scores were significantly improved using the robotic system over the 5-week period. During a total of 50 robotic cannulation procedures, 48 procedures scored between 21/35 and 34/35, indicating a competent performance and two cannulation procedures achieved a score of 35/35, indicating an excellent performance. Although a significant improvement over the 5-week study period was observed for the overall IC3ST performance scores with CCs, 20 cannulation procedures achieved a score between 7/35 and 20/35 and 30 procedures scored between 21/35 and 34/35, with no operators achieving an excellent procedure score of 35. This illustrates the intuitive nature of the robotic system as the majority of operators demonstrated a performance of a high standard at an earlier stage.

MSCs, although inferior to the robotic system, also demonstrated some advantages when compared with CCs; a significant reduction in the number of catheter-tip movements as well as vessel wall hits was seen once a learning curve plateau was reached. Interestingly, with MSCs, the learning curve plateau was consistent for all metrics, but varied with CCs. Although not directly quantified in this study, we observed that with experience, participants demonstrated cognitive improvement in performance by developing different cannulation strategies using MSCs and were able to keep the catheter low in the arch whilst directing the wire into the vessel by manipulating and steering its tip. By contrast, with CCs, it was necessary to advance the catheter in closer proximity to the vessel ostium before guiding the wire through its lumen. We found no significant difference at any time point with regard to total IC3ST performance scores between MSCs and CCs. However, subcategory analysis revealed that participants demonstrated increased awareness of areas of significant embolic risk while using MSCs compared with CCs after week 3, most likely secondary to enhanced catheter control. When considering total number of movements, wall hits and IC3ST scores, poorer performance with MSCs was seen in the first week, after which operators improved significantly. We believe that this is the result of subjects adapting to the MSC control handle, as suggested by subjects in the self-report questionnaires.

Surprisingly, subjects took significantly longer in cannulating all four arch vessels with both RC and MSCs compared to CCs. Novice subjects, however, often assume that faster completion of a technical task represents competence. Speed of task completion has been used previously to assess competency during surgical procedures; a fast but unskilled operator, however, is less desirable than a slow, skilled operator. Faster completion of a procedure, therefore, is at best a crude measure of technical skill, and cannulation times alone do not reflect overall performance as demonstrated by IC3ST scores and all other metrics, especially for robotic cannulation techniques.

Study limitations

This article assessed the impact of new endovascular technologies upon training for vessel cannulation and catheter manipulation skills. Our study is limited by the use of invitro phantoms, as these experimental models do not reflect all the challenges of catheter navigation in atherosclerotic aortic arches and the carotid bifurcation within a clinical setting and even high-fidelity simulators can only replicate a subset of actual clinical scenarios. In addition, the metrics used in this study are surrogate markers of embolisation risk and technical performance, and are in no means a substitute to clinical endpoints. More importantly, catheter manipulation is only a small part of the procedure as a whole; there are numerous factors contributing to the long learning curve of the endovascular specialist and they span technical skills as well as non-technical skills, such as patient selection, anatomical awareness and teamwork that have not been directly studied here. Our results are also reliant on the level of the subject’s motivation for performing well in a simulated environment with no perceived risk of adverse outcome, and, therefore, may have been influenced by the individual subject’s attitude and aptitude for new skill acquisition.

Finally, the current size of the robotic device does not justify its widespread use in arch vessel cannulation procedures. Further catheter development for optimisation
for use in the arterial tree and studies using this intuitive technology in the clinical environment are essential for evaluating the systems’ long-term safety and efficacy.

Conclusion

Using this model, novice subjects acquired rudimentary endovascular skills in a 5-week training programme using both conventional and more advanced endovascular catheters. MSCs, although more intricate, do not seem to take longer to master and in some areas offer clear advantages with regard to positional control, at a faster rate. RCs seem to be the most intuitive and advanced skill acquisition occurs with minimal training. Robotic endovascular technology may have a significantly shorter path to proficiency allowing an increased number of trainees to attempt more complex endovascular procedures earlier and with a greater degree of safety.

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Conflict of Interest

Institution level support from Hansen Medical and PolyDiagnost.

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