Time-Action Analysis of Catheter Manipulation During Navigation Tasks in Bifurcations

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*Endovascular intervention is a form of minimally invasive intervention that allows catheters to be placed in practically any location of the vascular tree. However, to provide access to all these remote locations, an extensive array of catheters is needed. A specific catheter is choose based on experience, without any objective indication of its suitability during the actual procedure (Bakker, N. H., Tanase, D., Reekers, J. A., and Grimbergen, C. A., 2002, "Evaluation of Vascular and Interventional Procedures with Time—Action Analysis: A Pilot Study," J. Vasc. Intervent. Radiol., **13**(5), pp. 483–488). The aim of this study is to evaluate several catheters using time-action analysis during a navigation task in bifurcations of various geometries. The relation between the geometry of bifurcations, the catheters, and the time taken to perform specific actions is investigated. Nine novices manipulated five widely used selective catheters with a 0.035" guidewire in a model. In the model, four bifurcations of various diameters and angles were selected. Each bifurcation was cannulated six times with two different yet suitable catheters. The participants had no direct vision of the model but navigated the instruments using the images that were captured by a camera and displayed on a screen. All images presented to the participant were recorded and used for detailed time-action analysis of the various actions to cannulate a branch (e.g., catheter or guidewire retracted, rotated, and advanced). On average, the participants needed 28.3 s to cannulate a branch. When the ratio between the diameter of the main and side branch was high, the average time per task increased significantly, as did the number of attempts to navigate into a branch. However, neither the choice between the two suitable catheters for each bifurcation, nor the angles of the bifurcation made a significant difference in navigation time. Time-action analysis enabled objective measurement of the time spent on various actions to cannulate a branch. The results revealed that most time was spent on retracting and rotating the catheter. This was comparable for all catheters and branches, showing that all the instruments were manipulated in a similar way and presented the same difficulties.* [DOI: 10.1115/1.4025188]

Keywords: interventional radiology, time-action analysis, navigation, selective catheters, bifurcations, geometry, instrument manipulation

Introduction

Endovascular interventions present many advantages for the patients, such as less pain and faster recovery, but for the interventionalist, they take a relatively long learning curve to be fully mastered. Dexterous manipulation of the instruments is essential in navigating the desired vessel to reach the target area and determines, to a great extent, efficiency and success rate [1]. Besides dexterity, one of the key issues is selecting the appropriate catheter (shape, diameter, and material) from the large choice of available instruments [2].

Catheters and guidewires are selected by the interventionalist based on the procedure and the patient's anatomy. Residents, fellows, or clinicians in training learn to choose the correct tool from colleagues. This choice is made without any objective data on the catheter's suitability for the procedure at hand and testing the mechanical properties of catheters and guidewire cannot predict the success of the instruments in real clinical procedures [3].

In previous studies, time-action analysis was described as valuable for instrument development, objective evaluation of instruments, and performance measurement for education and training. In fact, time-action analysis has successfully been used to evaluate laparoscopic and orthopedic surgical procedures [4–6] and could enable detailed evaluation of specific parts of a procedure [5]. Bakker et al. [3] used time-action analysis to objectively measure the duration and frequency of specific actions performed during a peripheral vascular procedure and to provide valuable insights in the difficulties that the user encountered. Detailed insights into the time spent on different parts of a whole intervention were analyzed. In our study, we were interested in the actions taken to cannulate a branch. Therefore the instruments manipulations had to be analyzed in much more detail.

The aim of this study was to use time-action analysis to investigate the relation between the geometry of bifurcations and selective catheters when navigating endovascular instruments for cannulating a branch. Novice participants were asked to manipulate endovascular instruments in a transparent model and navigate into bifurcations of various geometries. All instrument movements were recorded and the videos were thoroughly analyzed following a precise taxonomy of actions.

Materials and Methods

Model. A transparent geometric model (Fig. 1) made of acrylic glass was used to mimic the geometry of various bifurcations. This model contains 38 vessels with a diameter between 5 mm

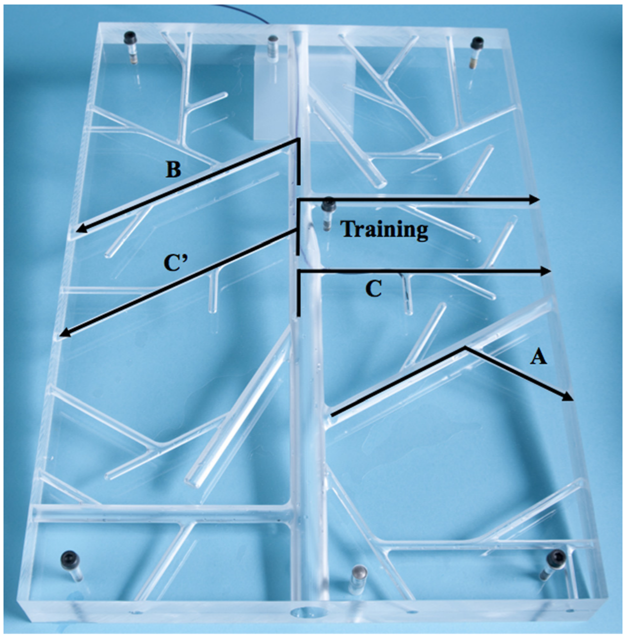

Fig. 1 The transparent model. The arrows marked A, B, C, C', and Training show the selected bifurcations that were included in the experiment.

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(0,19") and 20 mm (0,78"), and bifurcations with 90 deg, 60 deg, or 30 deg angles, each reachable from their acute or obtuse side.

Bifurcations. Four bifurcations were chosen in the model to represent bifurcations from the human anatomy (Table 1 and Fig. 1): a bifurcation in the leg A, the celiac trunk B, and two anatomical cases for the renal arteries, i.e., one bifurcation with a 90 deg angle C, and one with an inferiorly acute angle C'.

Instruments. Five common selective catheters for peripheral endovascular practice were selected for inclusion in the experiment: 5Fr, 65 cm (2,1'), Berenstein (BERN), Vertebral (VER), Renal Double Curve (RDC), Renal Curve 2 (RC2), and Cobra 2 (C2) (Cook Medical, Bloomington, IN; U.S. and Merit Medical Systems, South Jordan, UT.). Catheters presenting reverse curves, such as Sidewinder, were not included in the study as reforming the curve can be difficult for novices [7].

Following the guidelines of Kessel [7] and Schneider [2], two suitable catheters were selected for each bifurcation (Table 1). These selected catheters were manipulated together with the same 0.035" guidewire (coated, fixe core, 260 cm (8,5'), straight tip, Kimal, Bromsgrove, Worcestershire, UK). The straight tip guidewire was selected, as it is easy to manipulate for novice participants and does not need to be kept wet at all time. Only one guidewire was included in this study, in order to enable us to study the relation between the chosen selective catheter and the geometry of the bifurcation apart from the possible influence of the properties of the guidewire.

Setup. The model was placed in water in order to reduce friction between the catheters and the guidewire, and all catheters were flushed. The catheters were introduced in the model through a 6Fr introducer (11 cm (4,3"), Cordis, Bridgewater Township, NJ). The participants had no direct vision of the model but navigated the instruments using the images that were captured by a webcam (2 megapixel, Logitech, Morges, Switzerland) and displayed on a screen (black and white images, 30 fps, pixel matrix of 960 × 720, field of view 40 × 30 cm (15,7" × 11,8")), to represent X-ray images. All images presented to the participant were recorded and used for later analysis.

Participants. Nine right-handed volunteers (between 24 and 32 years old) with no prior experience with the manipulation of endovascular instruments participated in the experiment. We explicitly chose novices to have participants with an equal level of experience.

Procedure. Four bifurcations, selected in the model for inclusion in the experiment, were approached and passed six times with two different catheters. This number of repetitions allowed us to obtain information on the variability of the time taken per task, while limiting the total duration of the session to 1 h and preventing introducing bias due to fatigue of the participant. Consequently, each participant had to complete 48 tasks (6 × 2 × 4 = 48) to complete the session. The order of the series (bifurcation-catheter) was randomized for all participants.

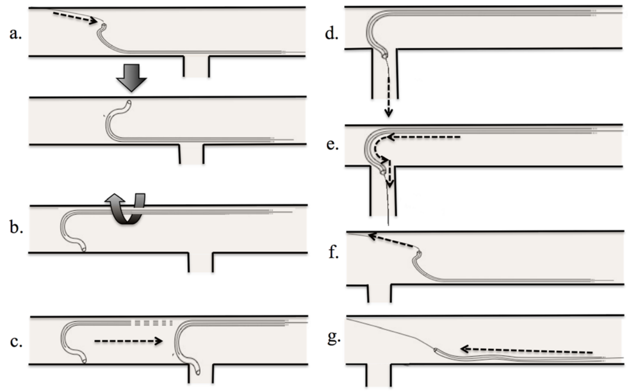

Fig. 2 Taxonomy of the actions on the catheter and guidewire. (*a*) Guidewire retracted. (*b*) Catheter turned. (*c*) Catheter retracted. End of (*c*) catheter in the bifurcation (tip of the catheter is in the bifurcation). (*d*) Guidewire advanced (in the target artery). (*e*) Catheter advanced (in the target artery). (*f*) Miss-guidewire (guidewire advanced in the main branch). (*g*) Miss-catheter (catheter advanced in the main branch).

Task. All the participants received the same written instructions explaining the basic manipulation of catheters and guidewires. Then the participants practiced in the model using the Cobra2 catheter to pass the training bifurcation two or three times (Fig. 1). The participant was standing for all manipulations.

Taxonomy of Actions. All the recorded manipulations were analyzed after the experiment. Each task was divided into elementary actions according to a strictly defined taxonomy so that no overlap existed among the eight actions of the catheter and guidewire (Fig. 2). The action "Miss-guidewire" and "Miss-catheter" specifically described the actions that had to be performed after missing the entrance of the target branch, when the instrument was brought back to the starting position. The actions "Mistakes" and "Other" were added to the classification. The action "Mistakes" corresponded to errors performed by the participant regarding the manipulation of the instrument. Finally, the action "Other" captured all remaining events of the taxonomy; in this

Table 1 Anatomic branches, chosen bifurcation and selected catheters

	in vivo		In the model			
	From	To	From	To	Name	Selected Catheters
Artery/Branch Diameter	Common femoral artery 8–13 mm [8] (0,31"–0,51")	Deep femoral artery 4–8 mm [8] (0,15"–0,31")	Main branch 10 mm (0,39")	Side branch 5 mm (0,20")		
Angle	Obtuse angle		60 deg		**A**	BERN, VER
Artery/Branch Diameter	Abdominal aorta (at the celiac level) 15–20 mm [9] (0,59"–0,79")	Celiac trunk 7–9 mm [7] (0,28"–0,35")	Main branch 15 mm (0,59")	Side branch 10 mm (0,39")		
Angle	Inferiorly acute angles		120 deg		**B**	RDC, RC2
Artery/Branch Diameter	Abdominal aorta (below the renal) 15 [9] (0,59"–0,87")	Renal arteries 5–6 mm [9,10] (0,20"–0,24")	Main branch 20 mm (0,79")	Side branch 5 mm (0,20")		
Angles	**C**: Branches at 90 deg angles **C'**: Inferiorly acute angles		90 deg 120 deg		**C** **C'**	RDC, C2 RDC, RC2

group, 89% of the events corresponded to waiting time. Each task was analyzed from the first action on the instruments till the last movement after having successfully cannulated the target branch.

Analysis

Each recording was played back in order to note the starting moment of each action, the number of actions, and the number of attempts for completing each task. The data were collected in a spreadsheet program (Microsoft Office Excel 2011, Microsoft, Redmond, WA). For each series, the time spent on all actions was averaged for each participant across the six trials that they performed. From these averages the mean and standard deviation (SD) across participants were calculated. Thus, SD corresponded to the variation among the participants. The results were statistically analyzed by using the Student's paired t-tests with two-tailed distributions. Differences between the two compared groups were considered to be significant if the p-value was smaller than 0.05.

Results

A total of 12,134 s manipulation time was analyzed. Participants took on average 28.3 s ± 15.0(SD) to pass a bifurcation. The nine participants presented comparable mean (between 34 s and 19 s) and standard deviation (5–15 s), except for one volunteer that presented higher value with a mean of 42.1 s ± 28.6(SD). Since all participants performed the task in the same manner, they were all included in the study. A learning effect was observed. Between 38 s and 38.5 s was taken on average to perform one task in the first two series, 30.2 s for the third, and from 21 s to 25 s for the final five. The learning curve was explained by the combined reduction of the number of actions per task and the mean time to perform each action.

Each bifurcation was approached with two different suitable catheters. For each bifurcation, the Student's paired t-test revealed no significant effect on the average time for one task, between the two catheters (Fig. 3). These results showed that, in our experiment, the choice of a catheter for a specific bifurcation between two suitable ones had no influence on the performance in terms of mean time to perform a task.

Moreover, no significant influence was found between the angle of the bifurcations and the navigation time. However, clear differences were observed between the four selected bifurcations. These bifurcations were divided into two groups based on their geometric similarities, denoting with Q, the ratio between the diameter of the main and side branch. The first group encompasses bifurcation A and B with $Q \leq 2$ ($Q_A = 10/5$, $Q_B = 15/10$) with a mean time per task $t_{A-B} = 20.3$ s ± 4.8(SD), the second group C and C' with $Q = 4$ ($Q_C = Q_{C'} = 20/5$), $t_{C-C'} = 36.1$ s ± 12.0(SD). The mean time per task for each group revealed a significant effect ($p < 0.01$). This effect was explained by a significant increase ($p = 0.012$) of the mean number of attempts, or tries, needed to complete a task in the group C–C', 1.74 ± 0.62(SD), compared with the group A–B, 1.18 ± 0.14(SD).

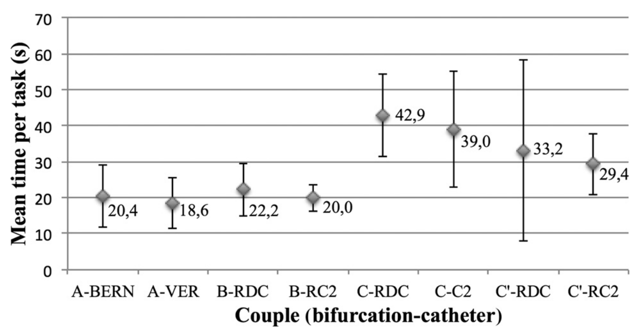

Fig. 3 Mean time for one task for each couple (bifurcation-catheter)

For each action, the mean cumulated action duration as a percentage of the average total task time was investigated (Fig. 4). In total, 64% of the time was spent on the manipulation of the catheter, 29% on the guidewire. The most time was spent on retracting (25%) and orienting/rotating the catheter tip (24%). The mean cumulated action duration of each action did not vary significantly across the four selected bifurcations of the experiment.

Discussion

In this study, we measured the time taken for specific actions during navigation of bifurcations. The mean time to complete the task differed between the bifurcations. The geometry of a bifurcation, characterized by the ratio Q between the diameter of the main and target branches, had a significant influence on the navigation time and; therefore, on the efficiency of the navigation. When the ratio Q between main and side branch diameter was large, the average time to pass a bifurcation and complete the task increased significantly, as did the number of attempts to navigate into a branch. For each branch, no significant difference was found between the two selected catheters in terms of navigation time. The angle of the bifurcations did not have a significant effect, either.

The current study used a simplified rigid phantom model and did not include physiologic flow features seen in human subjects, such as flow or vessel compliance. In addition, water was used in the model, which has a lower viscosity than blood but enabled the use of a webcam for guidance. The lack of the mentioned physiologic features may have induced bias in our study. However, we believe that these features have a very limited influence on the mean time per task and, more generally, on the total task time.

First, as regards the flow, conventional 5Fr catheters and a 0.035" straight guidewire that are typically used for peripheral interventions were used in this experiment. We are not aware of any study that shows that the maneuverability of endovascular instruments of the 0.035" system is influenced by flow features. In our experience, their stiffness is too high and the presence or lack of flow does not make a significant difference. In particular, neither the straight tip of the guidewire nor the tip shape of the catheter is likely to follow or curve due to the flow in a manner that could be expected from much thinner instruments, such as the catheters and guidewires from the microsystems [11].

Second, the main effect that the viscosity of the fluid may have had is on the friction between the instruments. It is known that dry instruments do not allow smooth sliding and that friction between the instruments is reduced by keeping them wet. In fact, during interventions, the guidewires are often kept in heparin–saline solution or are, at least, wiped with heparin–saline solution-soaked gauze before use [2]. Furthermore, catheters are flushed and wiped with the same liquid before been placed [2] in order to remove the air bubbles and to assure good lubricity between the guidewire, catheter, and sheath. Additionally, the catheter is intermittently flushed throughout the intervention [2]. Although the viscosity of the heparinized saline is unknown to us, its composition indicates that it is water based, with sodium chloride in water, and some heparin sodium at a given concentration. In our experiment, we reduced friction between the instruments by flushing the catheters with water before the beginning of the tasks and by keeping the guidewire wet. As the viscosity of heparinized saline is similar to water, we believe that the use of water, instead of blood, did not affect the friction and, therefore, the smooth manipulation of the instruments.

Consequently, although including the mentioned physiologic features in the study would improve the realism of the model and the task, it would probably have only minor effects on the task performance. We believe that catheters and guidewires would have been manipulated in a very similar way to cannulate the branches and, therefore, the relative contribution of a physiologic

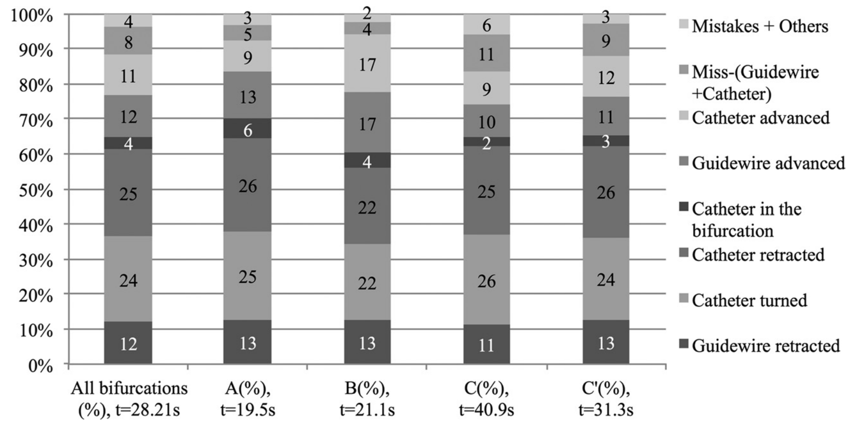

Fig. 4 Mean cumulated action duration as a percentage of the mean task time, t, per bifurcations

flow and fluid viscosity on the total task time and the separate steps is negligible. Further testing with a model that has flow features and liquid with viscosities close to blood is necessary to confirm these assumptions.

On the contrary, lack of vessel compliance may have had a noteworthy effect on the manipulation time as, in our case, the vessel walls and the bifurcations provided extra support to the instruments. In this respect, some of the manipulation steps could have been influenced more than other by this support, especially the actions "Guidewire advanced (in the target artery)" and "Catheter advanced (in the target artery)." The compliancy of vessels may make these actions more difficult to accomplish, or may require more careful handling from the manipulator. It is also possible that some of the catheters would behave in a different way in a more compliant physiology. If so, then it is possible that differences arise between the catheters suitable for a given geometry that were not observed in the current study. Alternatively, one could argue that a model with stiff walls is more representative of sick vessels, such as the ones that present arteriosclerosis, which are the vessels that need to be cannulated and treated during an intervention.

The percentage of time spent on each action presented a similar pattern for all branches and catheters. In fact, the participants manipulated all the selected catheters in a similar way when performing the cannulating task in the model. Furthermore, the choice of the catheter was not critical for a single bifurcation. This suggests that small variations between catheters, appropriate for a bifurcation, are of minor importance for navigation with novices. This result is in line with the general practice, where the preference of the interventional radiologist is usually decisive when several selective catheters may be suitable for a given peripheral artery [2,7]. This result may help developers in specifying requirements for the geometry of new selective catheters.

In the current study, time-action analysis was used to compare objectively the performance of simple and widely used catheters in various branches. Using a similar method, it would be interesting to evaluate the performance of complex catheters with experienced manipulators. Furthermore, a clinician could wish to evaluate a new selective catheter before using it on patients. A standardized method to analyze the navigational capabilities of different instruments for various branches would enable to assess risk, limitations, and expected benefits to be assessed before using a tool on patients.

The ratio between the diameter of the main and target branch of the bifurcation had a major influence on the number of attempts needed to navigate into a particular branch. From a clinical perspective, this result emphasizes the need for a specific training for early trainers. With each failed attempt at vessel cannulation, the risk of liberation of emboli, dissection, perforation, or generally vessel trauma caused by the catheter head increases [1,12,13]. During early training, the manipulator has to learn first to pick a selective catheter that corresponds to the target bifurcation. If the tool is correctly chosen, the remaining difficulty is not linked to the angle of the bifurcation but to the relative diameter of the vessels and the manipulation of the instruments. In our case, the most time-consuming tasks were retracting and orienting/rotating the catheter tip, corresponding together to about half of the time spent on navigating the instruments.

The current study used time-action analysis enabled objective measurement of the duration and frequency of actions performed to cannulate a branch. A detailed picture of the time spent on various actions was obtained and the relationship between the geometric of the bifurcations and catheters could be investigated. It was observed that minor differences in the shapes of a selective catheter had limited influence on the navigation time. Therefore, it would be interesting for the development of new instruments and technics to focus on more difficult, or time-consuming tasks, e.g., orienting the catheter tip, rather than on the exact geometry of the tool.

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