The use of virtual reality for carotid artery stenting (CAS) training in type I and type III aortic arches

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The use of virtual reality for carotid artery stenting (CAS) training in type I and type III aortic arches.

AIM: *Simulation has been proposed to improve learning curves in carotid artery stenting (CAS), but previous studies have only evaluated CAS simulation in a single type of arch usually either type I or type II. The aim of our study is to define the use of virtual reality for CAS training in type I and type III aortic arches for novice operators.*
MATERIALS AND METHODS: *Fifty experienced interventionalists and fifty novice trainees with no prior experience with endovascular procedures performed a virtual CAS in a type I aortic arch case and one in a type III arch case. They trained on simulator for two hours and then repeated the procedures. Data of the procedures were collected and analysed.*
RESULTS: *Among novice operators, 38 out of 50 ended the first procedure on type I arch (76%) and 32% (16 out of 50) concluded the first procedure on type III arch ($p < .05$). After training, 100% of novice ended the easy case and 56% (28 out of 50) concluded the difficult case ($p < .05$). All experienced operators successfully carried out the simulations. The simulator induced greater improvement among novice in type I arch rather than in type III arch. Performances of experienced didn't improve significantly. Among novice, virtual performances of "difficult" cases were significantly worse than those of "easy" cases, both before and after training.*
CONCLUSIONS: *Simulator is an effective tool for training of novice operators in type I aortic arch; on the contrary its role has yet to be established in type III aortic arch.*

KEY WORDS: CAS, Training, Virtual reality

Introduction

Carotid artery stenting (CAS) has been considered as a possible alternative to the traditional carotid endarterectomy (CEA), for the treatment of carotid artery stenosis [1]. According to the current American Heart Association guidelines, CAS must be performed by operators who have peri-procedural complication and mortality rates of 4-6% (Class IIa, Level B Recommendation) [2].
There is great evidence that achieving experience in CAS leads to a reduction of these rates [3]. At the present, training is carried out mainly on patients, with all risks concerning the safety of patients themselves.
Simulation has been proposed as a way to improve learning curves in CAS without risk of harm to operators or patients [4]. Virtual reality has proved to be of benefit in the acquisition of basic skills by novice operators [5], as well as in assessing technical skills [6], but previous studies have only evaluated CAS simulation with a single type of arch usually either type I or type II [7,8]. The aim of our study is to define the use of virtual reality for CAS training in type I and type III aortic arches for novice operators.

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Materials and methods

The Procedicus VIST

The Procedicus VIST system was specifically designed as a multimedia device for the training in endovascular techniques, including carotid stenting. The system consists of a personal computer with a software that simulates the fluoroscopy representation of the human arterial system; the operator can also select devices and catheters for the simulation.
The computer is coupled to a haptic module that uses a force feedback system; this provides tactile sensory information when the user inserts and manipulates standard angiographic catheters and guide wires (for example a resistance can be felt when passing throughout a lesion or a curve with a device).
The simulation interface device is designed to sense the simultaneous translation and rotation of up to three co-axial clinical tools, the flow of air from a syringe that shows a contrast injection on the display, pressure by fluid compressed and decompressed with an indeflator.

The study

After IRB approval for our clinical research, we enrolled 100 physicians representing multiple subspecialties: we asked 50 experienced interventional vascular surgeons and interventional radiologists (an average of 98 carotid angiographies and 82 CAS procedures per operator) to participate in our study primarily as a control for the validity of the simulator. The other 50 were novice vascular surgery and radiology trainees with no prior experience with endovascular procedures.

All participants were given introductory specific didactic instructions, provided by an expert interventional vascular surgeon, about the use of the simulator and the technical requirements for CAS; then they performed a procedure in a right bifurcation carotid stenosis in a type I aortic arch and a right internal carotid stenosis in a type III aortic arch.
They trained on the simulator for two hours; during this time each participant was given by the tutor a feedback about the most important errors committed; the tutor also provided the group of novice for suggestions and precepts about technical use of devices, such as how to manipulate wires and catheters and how to choose equipments correctly. At the end all participants repeated the two virtual procedures.
Data of performances were collected using a report of some simulator-derived metrics (Table I). The machine also recorded manoeuvres that could cause an adverse event (excessive manipulation of catheters/wires, early deployment of EPD, movement of deployed EPD (Embolic Ptotection Device), vessel spasm, vessel dissection).

Statistical analysis

Data obtained before and after training were entered into a database and analysed with Sigma Stat version 3.0. As data were normally distributed, the paired 2-tailed Student *t* test was used to analyze each participant's change in metrics recorded by the machine before and after training. ANOVA sample size test showed a power of 80% of the study. Nonparametric data were analysed using the "Chi-Square" test to assess a statistically significant difference. All values were represented as mean $\pm$ SD, and mean differences and correlations were considered significant at $P \leq .05$.

Table I - *Virtual performances before and after training*

	TYPE I ARCH			TYPE III ARCH		
	Befere	After	P. Value	Before	After	P. Value
Total time of procedure (min:sec)	30:18 ± 6:45	23:02 ± 5:53	< .05	38:39 ± 11:46	37:06 ± 11:44	NS
Contrast amount (cc)	11.74 ± 8.22	10.18 ± 6.89	NS	20.9 ± 6.9	22.1 ± 11.9	NS
Time of scope (min:sec)	18:37 ± 6:15	14:03 ± 3:22	< .05	26:48 ± 13:13	23:42 ± 9:07	NS
Time to the insertion of EPD (min:sec)	14:22 ± 4:16	9:52 ± 4:08	< .05	25:37 ± 11:15	23:43 ± 8:43	NS
Time to catheterisation of CCA (min:sec)	11:19 ± 4:38	8:22 ± 4:10	< .05	23:18 ± 10:55	21:36 ± 9:00	NS
Stent placement accuracy (mm)	5.16 ± 4.44	2.11 ± 1.58	< .05	3.8 ± 2.7	3.5 ± 2	NS
% of residual stenosis after stenting	64.6% ± 1.7%	52.2% ± 21.2%	< .05	72% ± 0%	57% ± 32%	NS
% of lesion covered with stent	90.2% ± 16.3%	97.1% ± 6.1%	NS	98.6% ± 4.4%	99.9% ± 0.5%	NS
Balloon placement accuracy (mm)	2.2 ± 1.5	2.9 ± 4.1	NS	3.0 ± 2.1	2.7 ± 1.6	NS
% of residual stenosis after ballooning	12.7% ± 15.2%	3.7% ± 6.8%	< .05	22.1% ± 12.5%	23.9% ± 14.3%	NS
% of lesion covered with balloon	75% ± 12.4%	87.9% ± 14.7%	< .05	97% ± 6.1%	95.8 ± 6.5%	NS
Catheter movements against vessel wall	11.8 ± 7.5	6.9 ± 5.9	< .05	49.6 ± 53.3	37.9 ± 37	< .05
Catheter movements without guidewire	3.6 ± 2.1	3.2 ± 1.9	NS	2.2 ± 2.6	3.5 ± 2.9	NS
Catheter movements near lesion	5.3 ± 3.4	4.9 ± 3	NS	3.1 ± 3.1	3.2 ± 2.9	NS
Guidewire movements near lesion	3.8 ± 2.1	2.9 ± 2.3	NS	4 ± 2.8	4.8 ± 3.9	NS
EPD movements during deployment	0.5 ± 0.3	0.6 ± 0.2	NS	0.70 ± 0.67	0.94 ± 0.14	NS
EPD movements after deployment	4.7 ± 2.2	4.4 ± 2.9	NS	5 ± 7.1	2.1 ± 2.4	NS

Results

Among non-experienced group 38 physicians out of 50 ended the first procedure on type I arch (76%) and 32% (16 out of 50) concluded the first procedure on type III arch ($p < .05$). After training, 100% of physicians in the novice group ended the easy case and 56% (28 out of 50) concluded the difficult case ($p < .05$). All experienced operators successfully carried out the simulations.

Some novel operators didn't end the procedure within 1 hour, so they voluntarily decided to drop.

In type I arch novels' virtual performances had a statistically significant improvement of some metrics after training (Table I).

In contrast, in type III arch training induced little improvements of virtual performances (Table I).

Collaterally, we observed that the performances of experienced improved after training both in type I and in type III arch, but the improvement wasn't statistically significant (Table II). To confirm the validity of the simulator, the performances of non-experts were compared to those of expert operators. We found that they were always significantly worse than those of the experts, both before and after training (p values < .05).

Type I aortic arch vs type III aortic arch. Among non experienced interventionalists, virtual performances of "difficult" cases were significantly worse than those of "easy" cases, both before and after training (Table III).

TABLE II - *Performances of experienced interventionalists*

	ARCH I			ARCH III		
	Befere	After	P. Value	Before	After	P. Value
Total time of procedure (min:sec)	18:29 ± 2:58	16:35 ± 2:00	NS	19:18 ± 1:49	18:36 ± 2:11	NS
Contrast amount (cc)	12.20 ± 4.14	12.62 ± 3.96	NS	12.5 ± 4.5	12.6 ± 4.9	NS
Time of scope (min:sec)	8:58 ± 2:22	8:52 ± 2:16	NS	11:15 ± 1:37	10:17 ± 1:33	NS
Time to the insertion of EPD (min:sec)	8:35 ± 1:43	7:49 ± 1:23	NS	10:48 ± 1:43	10:13 ± 1:19	NS
Time to catheterisation of CCA (min:sec)	6:48 ± 0:48	5:36 ± 0:50	NS	8:52 ± 1:44	8:00 ± 1:30	NS
Stent placement accuracy (mm)	2.7 ± 2.1	2.1 ± 1.2	NS	3.1 ± 1.2	2.0 ± 0.9	NS
% of residual stenosis after stenting	56.5% ± 18.1%	59.7% ± 16.5%	NS	72% ± 0%	68.8% ± 7.5%	NS
% of lesion covered with stent	94.9% ± 8.6%	95.6% ± 8.9%	NS	100% ± 0%	100% ± 0%	NS
Balloon placement accuracy (mm)	1.6 ± 1.2	1.3 ± 1.1	NS	2.4 ± 0.7	1.3 ± 0.7	NS
% of residual stenosis after ballooning	4.9% ± 4.9%	3.2% ± 2.3%	NS	16.7% ± 7.6%	13.9% ± 8.5%	NS
% of lesion covered with balloon	80.8% ± 17.0%	83.9% ± 17.1%	NS	100% ± 0%	100% ± 0%	NS
Catheter against vessel wall	9.27 ± 6.84	7.55 ± 3.88	NS	10.6 ± 2.8	8.9 ± 2.5	NS
Catheter without guidewire	4.55 ± 3.91	3.27 ± 3.29	NS	2.8 ± 1.6	2.5 ± 1.3	NS
Catheter near lesion	2.18 ± 1.25	1.55 ± 0.82	NS	1.5 ± 0.8	1.5 ± 0.8	NS
Guidewire near lesion	2 ± 1.41	1.18 ± 0.75	NS	1.9 ± 2.7	1.6 ± 2.3	NS
EPD movements during deployment	0.82 ± 0.40	0.86 ± 0.50	NS	0.45 ± 0.52	0.18 ± 0.40	NS
EPD movements after deployment	1.27 ± 2.33	0.36 ± 0.67	NS	0.7 ± 0.6	1.5 ± 4.5	NS

TABLE III - *Performances in type I arch versus type III arch.*

	BEFORE TRAINING			AFTER TRAINING		
	ARCH I	ARCH III	P. Value	ARCH I	ARCH III	P. Value
Total time of procedure (min:sec)	30:18 ± 6:45	38:39 ± 11:46	< .05	23:02 ± 5:53	37:06 ± 11:44	< .05
Contrast amount (cc)	11.74 ± 8.22	20.9 ± 6.9	< .05	10.18 ± 6.89	22.1 ± 11.9	< .05
Time of scope (min:sec)	18:37 ± 6:15	26:48 ± 13:13	< .05	14:03 ± 3:22	23:42 ± 9:07	< .05
Time to the insertion of EPD (min:sec)	14:22 ± 4:16	25:37 ± 11:15	< .05	9:52 ± 4:08	23:43 ± 8:43	< .05
Time to catheterisation of CCA (min:sec)	11:19 ± 4:38	23:18 ± 10:55	< .05	8:22 ± 4:10	21:36 ± 9:00	< .05
Stent placement accuracy (mm)	5.16 ± 4.44	3.8 ± 2.7	NS	2.11 ± 1.58	3.5 ± 2	< .05
% of residual stenosis after stenting	64.6% ± 1.7%	72% ± 0%	< .05	52.2% ± 21.2%	57% ± 32%	NS
% of lesion covered with stent	90.2% ± 16.3%	98.6% ± 4.4%	NS	97.1% ± 6.1%	99.9% ± 0.5%	NS
Balloon placement accuracy (mm)	2.2 ± 1.5	3.0 ± 2.1	NS	2.9 ± 4.1	2.7 ± 1.6	NS
% of residual stenosis after ballooning	12.7% ± 15.2%	22.1% ± 12.5%	NS	3.7% ± 6.8%	23.9% ± 14.3%	< .05
% of lesion covered with balloon	75% ± 12.4%	97% ± 6.1%	< .05	87.9% ± 14.7%	95.8 ± 6.5%	< .05
Catheter movements against vessel wall	11.8 ± 7.5	49.6 ± 53.3	< .05	6.9 ± 5.9	37.9 ± 37	< .05
Catheter movements without guidewire	3.6 ± 2.1	2.2 ± 2.6	NS	3.2 ± 1.9	3.5 ± 2.9	< .05
Catheter movements near lesion	5.3 ± 3.4	3.1 ± 3.1	NS	4.9 ± 3	3.2 ± 2.9	NS
Guidewire movements near lesion	3.8 ± 2.1	4 ± 2.8	NS	2.9 ± 2.3	4.8 ± 3.9	< .05
EPD movements during deployment	0.5 ± 0.3	0.70 ± 0.67	NS	0.6 ± 0.2	0.94 ± 0.14	NS
EPD movements after deployment	4.7 ± 2.2	5 ± 7.1	NS	4.4 ± 2.9	2.1 ± 2.4	NS

Discussion

Carotid artery stenting has emerged as a potential alternative to carotid endarterectomy [1]. The training of those performing these procedures has been discussed for long time in the medical literature [9]. Usually, operators must construct their own learning curve in the operating theater. This obviously involves a number of risks to the patient and the operator himself, who is in a state of psychological stress that can sometimes affect learning.
Moreover, not all procedures have the same degree of difficulty. In particular, in carotid stenting, the difficult selective access to the site of injury results in a greater number of movements of the catheters and guides by the operator, resulting in an increased risk of intraoperative complications [10].
In April 2004 the Food and Drug Administration (FDA) approved virtual reality (VR) simulators as good instruments for endovascular training [11]. Since that time, lot of studies have been carried on to demonstrate the effectiveness, realism and potential benefits of these instruments in training [12,13], such as reduction of time and expense for learning new skills, the totally absence of risk for patient and for the attending, illimitate repetition of procedures and immediate feedback of the tutor [14]. Up to now, however, formal role of VR in training programs is still unclear [4]. We tried to better understand how VR simulators could be used for training, particularly if the ultimate goal would be to use virtual reality as a stand alone training method prior to performing carotid artery procedures. Existing literature mostly demonstrates the benefits of virtual reality and CAS, but previous studies have only evaluated CAS simulation with a single type of arch usually either type I or type II [7,8].
This is the first study that examines how, through the simulator, we can infer a difference between easier performances (arch type I) and those more difficult (arch type III), especially when performed by inexperienced operators. As reported in our results, in fact, most of non-expert operators couldn't successfully perform virtual CAS in difficult anatomical approach, and the trainer demonstrated that there were significant differences if compared to performances in the easy case. Even if performances improved after training, there were still significant differences between virtual CAS in easy case and those in difficult case.
This point is important since the anatomical complexity of the case implies a greater manipulation of wires and catheters in the aortic arch, leading to a grater risk of peri-procedural strokes which can't be prevented by EPDs because they occur during the catheterisation phase.
Some of the major weaknesses of our study, however, regard the small sample size and small amount of training time. Van Herzeele et al. [15] reported that a two day training course had a benefit on virtual reality metric performance of experienced interventionalist, so if more time was dedicated to training further improvements and successful completion of the difficult cases may have been achievable too by inexperienced operators.

Conclusions

In our experience virtual reality simulator has proved to be an effective tool for training of non-experienced operators in type I aortic arch; on the contrary its role has yet to be established in type III aortic arch.
Moreover the potential transfer of competence to in vivo for carotid module will be a point of debate for future prospective randomised studies. If this point would be proved, virtual reality could become part of formal training program in CAS.

Riassunto

L'uso dei simulatori di procedure endovascolari è stato proposto in letteratura come un modo per migliorare le curve di apprendimento nello stenting carotideo (CAS), ma gli studi precedenti hanno valutato solo il ruolo del simulatore in procedure eseguite su un singolo tipo di arco aortico, di solito o di tipo I o di tipo II. Lo scopo del nostro studio è quello di definire l'uso della realtà virtuale per la formazione degli operatori meno esperti in procedure di stenting carotideo con archi aortici di tipo I e di tipo III.
Sono stati arruolati 50 chirurghi vascolari e radiologi con esperienza in procedure endovascolari e 50 tirocinanti in chirurgia vascolare e radiologia interventistica con nessuna esperienza in campo endovascolare. Tutti hanno eseguito una procedura di CAS virtuale in un caso con arco aortico di tipo I e una in un caso di aorco di tipo III, poi si sono allenati sul simulatore per due ore ed hanno ripetuto le procedure. Un report di misure registrate dalla macchina è stato utilizzato per raccogliere i dati, che sono stati inseriti in un database e analizzati utilizzando Sigma Stat ® 3.0.
Abbiamo osservato che il simulatore ha indotto un miglioramento delle performance dei non-esperti più significativo nell'arco di tipo I piuttosto che nell'arco di tipo III. Anche le prestazioni degli esperti sono migliorate, ma non in modo statisticamente significativo. A conferma della bontà della validità strutturale del simulatore, le performance dei non esperti sono state statisticamente peggiori rispetto a quelle degli operatori esperti. Tra i non esperti, le performances virtuali dei casi "difficili" sono risultate significativamente peggiori di quelle dei casi "facili", sia prima che dopo il training. Nella nostra esperienza il simulatore di stenting carotideo ha dimostrato di essere uno strumento efficace per la formazione degli operatori alle prime armi nell'arco aortico di tipo I, ma il suo ruolo è ancora da definire per quanto riguarda il III tipo di arco aortico.

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