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Vascular simulation training promotes clinical skill and reduces radiation in residents

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Vascular simulation training promotes clinical skill and reduces radiation in residents

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Running head: ST promote skill performance

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4 23 **Objective** This study aims to investigate the teaching effect of vascular simulation
5
6 24 training in rotating vascular residents. **Methods** A total of 95 vascular surgery residents
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9 25 were divided into a simulation training (ST) group and a conventional training (CT)
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11 26 group. The ST group received simulation training and conventional training, and the CT
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14 27 group only received conventional training. All data were collected, theoretical scores
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17 28 were assessed, and the technique parameters, complications and radiation damage of the
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20 29 procedures were analyzed. **Results** The mean scores (8.74 ± 1.09 vs 8.13 ± 1.31) and the
21
22 30 rate of willingness for retraining (93.62% vs 79.17%) in residents were higher in the ST
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24
25 31 group than in the CT group ($P<0.05$). The success rate of arterial puncture was
26
27 32 significantly higher in the ST group (78.72% vs 58.33% , $P=0.03$); however, the
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29
30 33 incidence of complications was similar between the two groups ($P>0.05$). The time of
31
32 34 the puncture procedure was significantly lower (9.56 ± 5.24 min vs 12.15 ± 6.87 min),
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35 35 and the comfort score of the patient (5.49 ± 1.72 vs 4.71 ± 1.57) was higher in the ST
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38 36 group than in the CT group ($P<0.05$). At the end of the assessment, the learning time for
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40 37 angiography (3.65 ± 0.64 mon vs 4.07 ± 0.77 mon) and the complete procedure time
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42 38 (33.81 ± 10.11 min vs 41.32 ± 12.56 min) were lower in the ST group than in the CT
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44
45 39 group ($P<0.01$). The fluo time for angiography (489.33 ± 237.13 s vs 631.47 ± 243.65 s)
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47
48 40 and the cumulative air kerma (401.30 ± 149.06 mGy vs 461.16 ± 134.14 mGy) were
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51 41 significantly decreased in ST group ($P<0.05$). **Conclusion** The application of a vascular
52
53 42 simulation system can significantly improve the clinical skills of residents and reduce
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55
56 43 the radiation damage from a single intervention procedure in patients.

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58 44 **Keywords:** Vascular surgery; Teaching modes; Simulation training; Traditional
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6 46 **Article summary**
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9 47 **Strengths and limitations of this study**
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11 48 ◆ The simulation training could promote the mean scores of residents

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14 49 ◆ The simulation training could significantly improve the clinical skill of residents
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17 50 ◆ The simulation training could reduce the radiation damage
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19 51 ◆ This study was not a prospective randomized study, and simulation training was not
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22 52 used for every resident; thus, the conclusions of this study should be confirmed in
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25 53 the future.
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68 INTRODUCTION

69 In recent years, with changes in the disease spectrum of Chinese patients, the
70 incidence of peripheral arterial disease has increased significantly, which has also
71 caused a severe economic and social burden [1]. Therefore, it is becoming increasingly
72 important to strengthen general and specialized vascular disease skills education in the
73 training of medical students and residents [2]. Vascular diseases involve multiple
74 disciplines, such as general surgery, cardiology, endocrinology and interventional
75 radiation, which also results in clinical training in vascular surgery being highly
76 complex, with integration and multidisciplinary characteristics [3]. In the past decade,
77 the practical skills training of resident has been mainly carried out through conventional
78 teaching (CT) modes. From theoretical knowledge to practical procedures, residents
79 lack sufficient practical procedures with simulation training; therefore, the true teaching
80 effect has not been ideal. Three-dimensional vascular simulator systems (Angiomentor
81 system, Simbionix, Ltd., Cleveland, OH) use digital simulation to quantify the vascular
82 interventional procedures of the cardiovascular, peripheral and cerebrovascular systems.
83 Students and residents can use the system to select cases for simulation training;
84 ultimately, the simulation training results are scored according to the operating steps of
85 the system. This simulation training can promote the mastery of vascular procedure
86 skills in residents and students [4-6].

87 The simulation system may be used as an educational tool for novice students and
88 residents, as it provides an opportunity to perform endovascular procedures in a safe

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4 89 environment. However, due to the late entry of simulation systems in China, there have
5
6 90 been no reports of the use of 3-dimensional vascular simulation systems in clinical
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9 91 practice teaching in the area of vascular surgery. The aim of this study was to assess the
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11 92 effect of simulation-based training on improving the technical performance and
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14 93 subsequent clinical procedures of residents in vascular surgery.
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17 94 **METHODS**

18 19 95 **Study procedures**

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22 96 A total of 95 vascular resident trainees at the First Affiliated Hospital of Xi'an Jiaotong
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24 97 University were recruited in this study from Jan 2015 to Dec 2018, and all residents
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27 98 needed to complete 6 months of endovascular training in vascular surgery. Thereafter,
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30 99 47 vascular residents received simulation-based vascular training (ST group) for two
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33 100 weeks, and then they completed the last clinical training. The other 48 residents only
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35 101 completed conventional clinical training (CT group) without the simulation course. A
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38 102 survey was administered to determine the demographics, academic degree, specialty
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41 103 level, and previous work experiences that may have been relevant in terms of the
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43 104 residents' ability to learn vascular interventional skills. This study was approved by the
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45 105 institutional review board of the First Affiliated Hospital of Xi'an Jiaotong University
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48 106 (XJTU1AF2014LSK-112), all of the patients provided written informed consent.
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51 107 Before the course was performed, the residents in the ST group received a
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53 108 standardized introduction to the endovascular simulator and performed a
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56 109 cerebrovascular angiography procedure. The 2-week curriculum consisted of theory
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59 110 teaching and 30-60 min lectures per day covering basic catheter-based interventions,
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4 111 cerebrovascular disease, superficial femoral artery disease and renal artery disease. The
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6 112 residents received 1-hour mentored simulator sessions per day and practiced carotid,
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9 113 renal and superficial femoral artery interventions. This course was performed by a tutor.
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11 114 Then, residents needed to complete the primary endovascular procedure with direct
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14 115 instruction. During the entire training process, each resident was required to complete
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17 116 the simulation training for no less than 1 hour per day. The course concluded with a
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19 117 final cerebrovascular angiography procedure performed on the simulator. The residents
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22 118 in the CT group underwent the basic 2-week curriculum consisting of theory teaching
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25 119 and 30-60 min lectures per day covering basic endovascular intervention procedures but
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28 120 without the simulation training course.

121 **Simulation system**

122 The vascular simulator system (Angiomentor system, Symbionix, Ltd., Cleveland, OH,
123 Fig 1) was composed of a standard desktop computer with software that simulated the
124 human arterial system in 3 dimensions, and any user could perform the endovascular
125 interventional procedures under the instruction of the system. This simulation system
126 was connected to a haptic pressure feedback module, which used a force feedback
127 system to detect external devices. When the users inserted the angiography catheters
128 and wires, injected contrast and performed the endovascular procedures with digital
129 subtraction angiography, all procedures could then be displayed on the screen in real
130 time. The user was able to select the device to be simulated through one monitor, and
131 the second monitor was used to display the simulated fluoroscopic image.

132 **Procedure evaluation**

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4 133 When the residents completed the training course, all residents received assessments of
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6 134 theoretical knowledge at 1 month and practical assessments at 6 months. The teaching
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9 135 expert group made the theoretical test questions based on the key points of vascular
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11 136 disease as well as the endovascular interventional procedures and technical points
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14 137 involved in vascular surgery clinical training, and then the residents completed the
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17 138 assessment independently. Finally, the expert group determined the student's score
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19 139 based on the results of the test. The score range was 0-10, and a passing score was
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22 140 defined as a score higher than 7. All residents completed the arterial puncture procedure
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25 141 with the Seldinger technique and performed the cerebrovascular angiography procedure.
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27 142 The success criterion of arterial puncture was defined as follows: all puncture
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29 143 procedures were successfully completed, and the sheath was successfully inserted into
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32 144 the femoral artery. If the residents failed to complete the processes of puncture and
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35 145 sheath placement, which was defined as a puncture failure, then the puncture was
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38 146 performed by the teacher. The puncture success rate, puncture time and complications
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41 147 were recorded, and the comfort scores of the patients during the puncture procedure
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43 148 were assessed with a numerical rating scale (NRS). The NRS score ranged from 0 to 10,
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45 149 where 0 indicates worst uncomfortable pain and 10 indicates comfortable pain [7].
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48 150 Subsequently, the residents needed to complete the cerebrovascular angiography
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51 151 procedure. The evaluation indicators of angiography were as following: learn time to
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53 152 complete procedure (LTP), time of complete procedure at the final test (TCP), fluo time
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56 153 of procedure (FTP), cumulative air kerma (CAK) and dose area product (DAP). LTP
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58 154 was defined as the time required from the beginning of training to the completion of the
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4 155 first angiography procedure independently. TCP, FTP, CAK and DAP were defined as
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6 156 the time of procedure and related parameters of the assessed angiography procedure at
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9 157 the end of the training.
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11 158 **Patient and public involvement**

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14 159 Patients and the public were not involved in the design or planning of the study.
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17 160 **Statistical Analysis**

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19 161 All data were analyzed using SPSS v. 11.0 (SPSS, Chicago, IL, USA), and $P < .05$ was
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22 162 considered statistically significant. To test the difference between groups, we used
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24 163 Chi-square analysis for categorical variables and Student's t-tests for continuous
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27 164 variables, and we tested the significance of the difference between 2 independent
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30 165 proportions when the results were presented as percentages.
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32 166 **RESULTS**

33 167 **The baseline data of the two groups**

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37 168 This study included 48 residents and 47 residents who were retrospectively recruited in
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40 169 this study, and there was no significant difference in baseline data between the two
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43 170 groups (Table 1, $P > 0.05$). There were 44 males and 4 females who received CT training,
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46 171 with a mean age of 33.13 years, and 42 males and 5 females who received ST training,
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49 172 with a mean age of 33.91 years ($P > 0.05$). The background academic degrees were
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52 173 bachelor and postgraduate degrees in the CT and ST groups ($P > 0.05$), and 30 and 26
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55 174 residents had a specialty background in vascular surgery in both groups (62.50% vs
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58 175 55.32%, $P > 0.05$). The clinical work experience of most residents was less than three
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60 176 years in both groups (66.67% vs 57.45%, $P > 0.05$).

177 **The theoretical scores between both groups**

178 All residents passed the training test; however, the mean scores of the residents were
179 higher in the ST group than in the CT group (8.74 ± 1.09 vs 8.13 ± 1.31 , $P=0.014$). After
180 the clinical training, the training satisfaction rates of all residents were similar (97.87%
181 vs 91.67% , $P>0.05$); however, when asked whether they wished to participate in the
182 training again, the residents in the ST group showed a higher willingness rate than
183 residents in the CT groups (93.62% vs 79.17% , $P=0.04$).

184 **The performance of arterial puncture in residents**

185 After the training, all residents underwent an arterial puncture test (Table 2), and the
186 success rate of the procedure was higher in the ST group than in the CT group (78.72%
187 vs 58.33% , $P=0.033$); however, the total puncture success rate was similar between the
188 two groups (95.74% vs 91.67% , $P>0.05$). The complications of the puncture sites
189 included bruising, hematoma, infection and pseudoaneurysm, and there was no
190 significant difference in the incidence of complications between the ST and CT groups
191 (17.02% vs 18.75% , $P>0.05$); however, the time of the puncture procedure was shorter
192 in the ST group than in the CT group (9.56 ± 5.24 min vs 12.15 ± 6.87 min, $P=0.002$), and
193 the comfort score of patients was higher in the ST group than in the CT group according
194 to the NRS scores (5.49 ± 1.72 vs 4.71 ± 1.57 , $P=0.023$).

195 **The outcome of cerebrovascular angiography**

196 All residents needed to complete the final cerebrovascular angiography test; the related
197 parameters are listed in Table 3. The residents in the ST group showed a shorter study
198 curve with a lower mean LTP than residents in the CT groups (3.65 mon vs 4.07 mon,

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4 199 $P<0.01$), and the TCP of the final test was higher in the CT group than in the ST group
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6 200 (41.32 min vs 33.81 min, $P=0.002$). The radiation damage-related parameters were
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9 201 recorded, and the residents in the CT group showed higher mean values of FTP (631.47
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11 202 s vs 489.33 s, $P<0.001$) and CAK than the residents in the ST group (463.16 vs 401.30
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14 203 mGy, $P=0.043$); however, the mean DAP value in both groups indicated no difference
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17 204 (128624.30 mGy.cm² vs 128012.10 mGy.cm², $P>0.052$).

205 **DISCUSSION**

206 The development of vascular surgery occurred relatively late in China; thus, the training
207 model used for vascular residents in most university hospitals has been the CT model;
208 however, traditional training did not improve residents' understanding and interest in
209 vascular surgery. Therefore, in past decades, there were fewer residents who chose
210 vascular surgery as a career option in China, which was consistent with the reports of
211 previous studies [7]. Therefore, improving residents' interest in vascular surgery and
212 promoting vascular clinical skills have been the main problems associated with vascular
213 surgery training [8]. Earlier studies have shown that compared with traditional training,
214 the use of network media, social media and simulation systems can achieve better
215 training results [9-11]. In this study, we used the vascular simulation system to assist
216 residents in clinical training. The results revealed that simulation training could
217 significantly improve the clinical practice effect of residents. The residents who
218 received the simulation training had significantly higher theoretical scores; in addition,
219 the interest level of residents was higher after simulation training. The vascular
220 simulation system could standardize complex vascular systems and different vascular

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4 221 lesions through analog calculations, which could help residents practice vascular skills
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6 222 training earlier and improve the interest level and skills of residents [3].
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9 223 After simulation training and basic training, residents need further vascular skills
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11 224 training. The basic skill procedure for vascular residents is arterial puncture. However,
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14 225 in clinical practice, it is impossible for residents to repeatedly perform the procedure
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17 226 during the treatment of patients. Therefore, in vitro simulation training has become the
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19 227 main teaching method in the training of vascular residents. It has been reported that
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22 228 simulation training can promote the clinical performance and vascular skills of residents
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25 229 [12]. Residents who received simulator training showed better clinical performance in
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27 230 the vascular surgery rotation, more motivation to learn, a shorter learning time and a
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30 231 lower number of clinical procedural errors, and the patients indicated a lower
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33 232 discomfort rate with the procedure [13]. In our study, the results confirmed that the
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35 233 residents who underwent the simulation training had a significantly higher success rate
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37 234 of arterial puncture, and the time of the puncture procedure was also significantly lower.
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40 235 Each step of the vascular procedure could be programmed and standardized in the
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43 236 simulation system. After the teacher's explanation and auxiliary training, it was easier
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46 237 for residents to develop standardized vascular skill habits and the correct procedural
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48 238 process. Finally, we evaluated the training effect with the cerebrovascular angiography
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51 239 procedure. Our results proved that the learning time of the angiography procedure and
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54 240 time of completed procedures were significantly lower in residents with simulation
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56 241 training; these results were consistent with previous reports [14]. This finding also
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59 242 confirmed that different simulation systems and teaching models could improve the
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4 243 effectiveness of clinical teaching and promote the understanding and proficiency of
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6 244 vascular practical skills.
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9 245 Furthermore, the final effect of clinical training should be assessed by the practice
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11 246 procedure of residents. Our study confirmed that vascular simulation training could
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14 247 significantly promote the practice skills of residents and promote the understanding of
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17 248 basic knowledge. Most cases of vascular disease teaching need to be performed under
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19 249 radiation; thus, simulation training could avoid radiation damage to teachers and
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22 250 residents. In this study, the results demonstrated that simulation training could decrease
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25 251 the fluo time and cumulative air kerma of the procedure, which meant that simulation
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27 252 training could reduce the radiation damage of patients and residents, and radiation
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30 253 protection was an important teaching ethics component in vascular surgery practice.
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33 254 However, due to the limitations of our teaching funding and the time course, only
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35 255 selective residents underwent the simulation training for 2 weeks, which was different
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38 256 from what occurs in advanced vascular centers. Other reports have shown that
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41 257 simulation training for 8 weeks can improve the procedure skills of residents, contribute
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43 258 to patient safety and have a positive impact on the career planning and choice of
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45 259 vascular surgeons [15].
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48 260 In conclusion, our results confirmed that a vascular simulation system could improve
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51 261 the clinical skills of residents and reduce the radiation damage received by patients and
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53 262 residents in endovascular procedures. Nevertheless, this study was not a prospective
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56 263 randomized study, and simulation training was not used for every resident; thus, the
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58 264 conclusions of this study should be confirmed in the future.
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8
9 267 Experts (AJE).

10
11 268 **Conflicts of Interest:** None.

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13
14 269 **Author Contributions:** All authors made contributions to the conception and design of
15
16 270 the paper. LY and YZ L contributed to the drafting of the work; LY, JLL and YML
17
18 271 contributed to the critical revision of the paper. All authors approved the final
19
20 272 manuscript for submission and have agreed to be accountable for all aspects of the
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22 273 paper.

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27 274 **Ethical approval:** The study received institutional review board approval.
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9 333 **Figure legends**

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11 334 **Figure 1.** The vascular simulator system (Angiomentor system, Symbionix, Ltd.,
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14 335 Cleveland, OH) used in this study simulated the vascular interventional procedures of
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17 336 the cardiovascular, peripheral and cerebrovascular systems in 3 dimensions.
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355 **Tables**

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Table 1 The baseline data of both groups

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Sex (M)	44 (91.67)	42 (89.36)	0.70
Age (years)	33.13±3.04	33.91±4.94	0.35
Academic degree			0.36
bachelor	22 (45.83)	26 (55.32)	
postgraduate	26 (54.17)	21 (44.68)	
Specialty background			0.48
vascular	30 (62.50)	26 (55.32)	
nonvascular	18 (37.50)	21 (44.68)	
Work experience			0.35
> 3 years	16 (33.33)	20 (42.55)	
≤ 3 years	32 (66.67)	27 (57.45)	

357 CT: conventional training; ST: simulation training; M: male.

358 *P* value, compared with the CT group

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Table 2 The performance of arterial puncture in residents

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Puncture success rate	28 (58.33)	37 (78.72)	0.033
Total puncture success rate	44 (91.67)	45 (95.74)	0.69
Complications from puncture	9 (18.75)	8 (17.02)	0.83
bruising	5 (10.42)	6 (12.77)	
hematoma	3 (6.25)	2 (4.26)	
infection	0	0	
arteriovenous fistula	0	0	
pseudoaneurysm	1 (2.08)	0	
time of puncture (min)	12.15±6.87	9.56±5.24	0.002
Comfort score of patients	4.71±1.57	5.49±1.72	0.023

366 CT: conventional training; ST: simulation training.

367 *P* value, compared with the CT group

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Table 3 The performance on cerebrovascular angiography in residents

	CT group (n=48)	ST group (n=47)	<i>P</i> value
LTP (mon)	4.07±0.77	3.65±0.64	<0.01
TCP (min)	41.32±12.56	33.81±10.11	0.002
FTP (s)	631.47±243.65	489.33±237.13	0.005
CAK (mGy)	463.16±134.14	401.30±149.06	0.043
DAP (mGy.cm ²)	128624.30±28982.22	128012.10±31035.08	0.92

377 CT: conventional training; ST: simulation training; LTP: learn time to complete
 378 procedure from beginning; TCP: time of complete procedure at the final test; FTP: fluo
 379 time of procedure; CAK: cumulative air kerma; DAP: dose area product
 380 *P* value, compared with the CT group

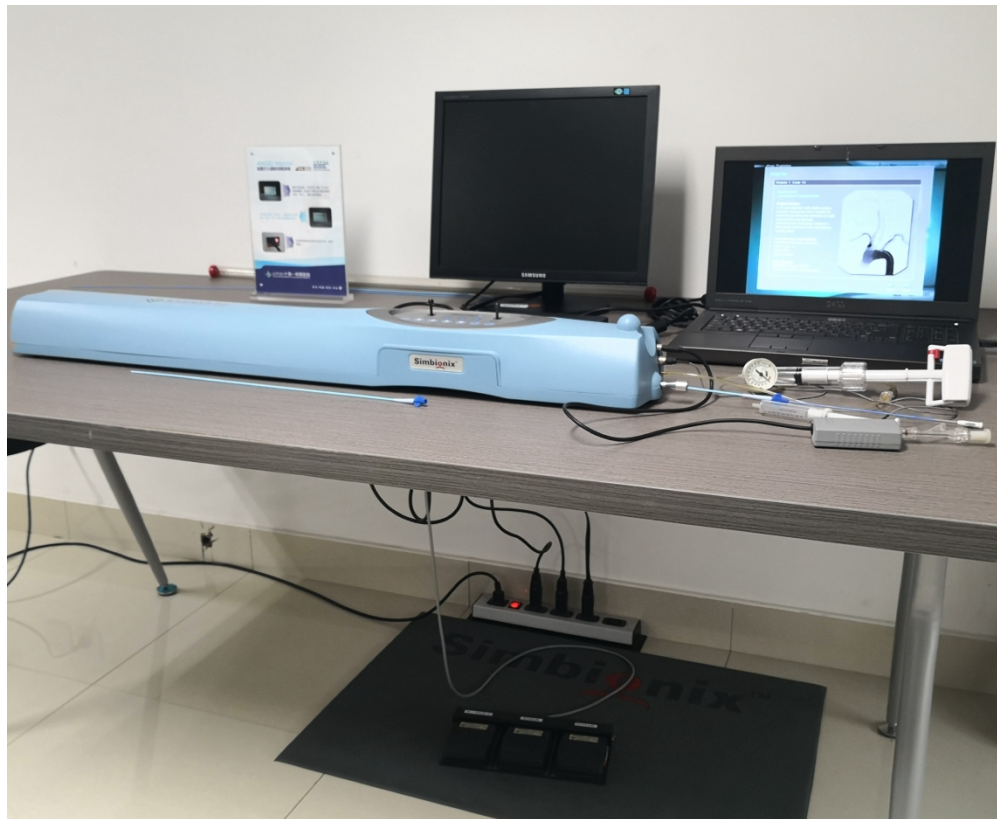


Figure 1. The vascular simulator system (Angiomentor system, Sionbionix, Ltd., Cleveland, OH) used in this study simulated the vascular interventional procedures of the cardiovascular, peripheral and cerebrovascular systems in 3 dimensions.

1099x897mm (72 x 72 DPI)

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1–2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1–2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3–4
Objectives	3	State specific objectives, including any pre-specified hypotheses	3–4
Methods			
Study design	4	Present key elements of study design early in the paper	4–6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4–6
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4–6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	4–6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4–6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4–6
Bias	9	Describe any efforts to address potential sources of bias	4–6
Study size	10	Explain how the study size was arrived at	4–6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4–6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	7

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	7
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7–9
		(b) Give reasons for non-participation at each stage	7–9
		(c) Consider use of a flow diagram	7–9
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7–9
		(b) Indicate number of participants with missing data for each variable of interest	7–9
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	7–9
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7–9
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	7–9
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	7–9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7–9
		(b) Report category boundaries when continuous variables were categorized	7–9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7–9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7–9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9–11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9–11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9–11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9–11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The effect of vascular simulation training on practice performance in residents: a retrospective cohort study

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4 1 **The effect of vascular simulation training on practice**
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6 2 **performance in residents: a retrospective cohort study**
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38 14 **Running head:** Effect of ST in residents
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4 23 **Abstract**

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6 24 **Objective:** This study aims to investigate the teaching effect of vascular simulation
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9 25 training in rotating vascular residents.

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11 26 **Design:** Retrospective cohort study

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14 27 **Setting and participants:** A total of 95 vascular residents were recruited from 2015 to
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17 28 2018 in a university affiliated center western China, and divided into a simulation
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19 29 training (ST) group and a conventional training (CT) group. ST group received
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22 30 simulation training and conventional training, and the CT group only received
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25 31 conventional training.

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27 32 **Primary outcome measures:** Theoretical scores were assessed, and the technique
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30 33 parameters, complications and radiation damage of the procedures were analyzed.

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32 34 **Results:** The mean scores (8.74 ± 1.09 vs 8.13 ± 1.31) and the rate of willingness for
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34
35 35 retraining (93.62% vs 79.17%) in residents were higher in the ST group than in the CT
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38 36 group ($P < 0.05$). The success rate of arterial puncture was significantly higher in the ST
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41 37 group (78.72% vs 58.33% , $P = 0.03$); however, the incidence of complications was
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44 38 similar between the two groups ($P > 0.05$). The time of the puncture procedure was
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47 39 significantly lower (9.56 ± 5.24 min vs 12.15 ± 6.87 min), and the comfort score of the
48
49
50 40 patient (5.49 ± 1.72 vs 4.71 ± 1.57) was higher in the ST group than in the CT group
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53 41 ($P < 0.05$). At the end of the assessment, the learning time for angiography (3.65 ± 0.64
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56 42 min vs 4.07 ± 0.77 min) and the complete procedure time (33.81 ± 10.11 min vs
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59 43 41.32 ± 12.56 min) were lower in the ST group than in the CT group ($P < 0.01$). The fluo
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44 time for angiography (489.33 ± 237.13 s vs 631.47 ± 243.65 s) and the cumulative air

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4 45 kerma (401.30 ± 149.06 mGy vs 461.16 ± 134.14 mGy) were significantly decreased in
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7 46 ST group ($P < 0.05$).

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9 47 **Conclusion:** The application of a vascular simulation system can significantly improve
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11
12 48 the clinical performance of residents and reduce the radiation damage from a single
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14
15 49 intervention procedure in patients.

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17 50 **Keywords:** Vascular surgery; Medical education & training; Teaching modes;
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20 51 Simulation training; Traditional teaching
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4 67 **Article summary**
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6 68 **Strengths and limitations of this study**
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9 69 ◆ The simulation training could promote the mean scores of residents
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11 70 ◆ The simulation training could improve the clinical performance of residents
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13 71 ◆ The simulation training could reduce the radiation damage
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15 72 ◆ The simulation training should be widely used in clinical teaching practice.
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18 73 ◆ The conclusions of this study should be confirmed via prospective randomized
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22 74 study.
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89 INTRODUCTION

90 In recent years, with changes in the disease spectrum of Chinese patients, the incidence
91 of peripheral arterial disease has increased significantly, which has also caused a severe
92 economic and social burden [1]. Therefore, it is becoming increasingly important to
93 strengthen general and specialized vascular disease skills education in the training of
94 medical residents [2, 3]. In the past decade, the practical skills training of resident has
95 been mainly carried out through conventional teaching (CT) modes (including
96 classroom teaching, lectures and surgical practice), and residents lack sufficient
97 practical procedures with simulation training from theoretical knowledge to practical
98 procedures, therefore, the true teaching effect was not ideal.

99 Three-dimensional vascular simulator systems (Angiomentor system, Symbionix, Ltd.,
100 Cleveland, OH) use digital simulation to quantify the vascular interventional procedures
101 of the cardiovascular, peripheral and cerebrovascular systems. Residents can use the
102 system to select cases for simulation training; ultimately, the simulation training results
103 are scored according to the operating steps of the system. This simulation training can
104 promote the mastery of vascular procedure performance in residents [4-6], and this
105 system provides an opportunity to perform endovascular procedures in a safe
106 environment as an educational tool for novice residents.

107 However, due to the late entry of simulation systems in China, there has been no
108 report of the use of 3-dimensional vascular simulation systems in clinical practice
109 teaching in the area of vascular surgery. The aim of this study was to assess the effect of
110 simulation-based training on improving the technical performance and subsequent

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4 111 clinical procedures of residents in vascular surgery.
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6 112 **METHODS**
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9 113 **Study procedures**
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11 114 A total of 95 vascular resident trainees at the First Affiliated Hospital of Xi'an Jiaotong
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14 115 University were respectively collected in this study from Jan 2015 to Dec 2018, 47
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17 116 vascular residents received simulation-based vascular training (ST group) for two weeks,
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20 117 and then they completed the last clinical training. The other 48 residents only completed
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23 118 conventional clinical training (CT group, including classroom teaching, lectures and
24
25 119 surgical practice) without the simulation course, and all residents needed to complete 6
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27 120 months of endovascular training in vascular surgery. A survey was administered to
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30 121 determine the demographics, academic degree, specialty level, and previous work
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33 122 experiences that may have been relevant in terms of the residents' ability to learn
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35 123 vascular interventional skills. This study was approved by the institutional review and
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38 124 ethics board of the First Affiliated Hospital of Xi'an Jiaotong University
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40 125 (XJTU1AF2014LSK-112), all of the patients provided written informed consent.
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43 126 Before the course was performed, the residents in the ST group received a
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46 127 standardized introduction to the endovascular simulator and performed a
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49 128 cerebrovascular angiography procedure. The 2-week curriculum consisted of theory
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51 129 teaching and 30-60 min lectures per day covering basic catheter-based interventions,
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54 130 cerebrovascular disease, superficial femoral artery disease and renal artery disease. The
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56 131 residents received 1-hour mentored simulator sessions per day and practiced carotid,
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59 132 renal and superficial femoral artery interventions. This course was performed by a tutor.
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4 133 Then, residents needed to complete the primary endovascular procedure with direct
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6 134 instruction. During the entire training process, each resident was required to complete
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9 135 the simulation training for no less than 1 hour per day. The course concluded with a
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11 136 final cerebrovascular angiography procedure performed on the simulator. The residents
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14 137 in the CT group underwent the basic 2-week curriculum consisting of theory teaching
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17 138 and 30-60 min lectures per day covering basic endovascular intervention procedures but
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19 139 without the simulation training course.

22 140 **Simulation system**

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24 141 The vascular simulator system (Angiomentor system, Symbionix, Ltd., Cleveland, OH,
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26
27 142 Fig 1) was composed of a standard desktop computer with software that simulated the
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30 143 human arterial system in 3 dimensions, and any user could perform the endovascular
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32 144 interventional procedures under the instruction of the system. This simulation system
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35 145 was connected to a haptic pressure feedback module, which used a force feedback
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38 146 system to detect external devices. When the users inserted the angiography catheters
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40 147 and wires, injected contrast and performed the endovascular procedures with digital
41
42 148 subtraction angiography, all procedures could then be displayed on the screen in real
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44
45 149 time. The user was able to select the device to be simulated through one monitor, and
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47
48 150 the second monitor was used to display the simulated fluoroscopic image.

51 151 **Procedure evaluation**

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53 152 When the residents completed the training course, all residents received assessments of
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56 153 theoretical knowledge at 1 month and practical assessments at 6 months. The teaching
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58 154 expert group made the theoretical test questions based on the key points of vascular
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4 155 disease as well as the endovascular interventional procedures and technical points
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6 156 involved in vascular surgery clinical training, and then the residents completed the
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9 157 assessment independently. Finally, the expert group determined the student's score
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11 158 based on the results of the test (including the detailed information of knowledge and
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14 159 practice). The theoretical score range was 0-10, and a passing score was defined as a
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17 160 score higher than 7. All residents completed the arterial puncture procedure with the
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19 161 Seldinger technique and performed the cerebrovascular angiography procedure. The
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22 162 success criterion of arterial puncture was defined as follows: all puncture procedures
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25 163 were successfully completed, and the sheath was successfully inserted into the femoral
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28 164 artery. If the residents failed to complete the processes of puncture and sheath
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30 165 placement, which was defined as a puncture failure, then the puncture was performed by
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32
33 166 the teacher. The puncture success rate, puncture time and complications were recorded,
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36 167 and the comfort scores of the patients during the puncture procedure were assessed with
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38 168 a numerical rating scale (NRS). The NRS score ranged from 0 to 10, where 0 indicates
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40 169 worst uncomfortable pain and 10 indicates comfortable pain [7]. Subsequently, the
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43 170 residents needed to complete the cerebrovascular angiography procedure. The
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46 171 evaluation indicators of angiography were as following: learn time to complete the
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48 172 procedure (LTP, defined as the time from the beginning of training to the completion of
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51 173 the first angiography independently), time of complete procedure at the final test (TCP),
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54 174 fluo time of procedure (FTP), cumulative air kerma (CAK) and dose area product
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56 175 (DAP). TCP, FTP, CAK and DAP were defined as the time of procedure and related
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59 176 parameters of the assessed angiography procedure at the end of the training.
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177 **Patient and public involvement**

178 Patients and the public were not involved in the design or planning of the study.

179 **Statistical Analysis**

180 All data were analyzed using SPSS v. 11.0 (SPSS, Chicago, IL, USA), and $P < .05$ was
181 considered statistically significant. To test the difference between groups, we used
182 Chi-square analysis for categorical variables and Student's t-tests for continuous
183 variables, and we tested the significance of the difference between 2 independent
184 proportions when the results were presented as percentages.

185 **RESULTS**

186 **The baseline data of the two groups**

187 This study included 48 residents and 47 residents who were retrospectively recruited in
188 this study, and there was no significant difference in baseline data between the two
189 groups (Table 1, $P > 0.05$). There were 44 males and 4 females who received CT training,
190 with a mean age of 33.13 years, and 42 males and 5 females who received ST training,
191 with a mean age of 33.91 years ($P > 0.05$). The background academic degrees were
192 bachelor and postgraduate degrees in the CT and ST groups ($P > 0.05$), and 30 and 26
193 residents had a specialty background in vascular surgery in both groups (62.50% vs
194 55.32%, $P > 0.05$). The clinical work experience of most residents was less than three
195 years in both groups (66.67% vs 57.45%, $P > 0.05$).

196 **The theoretical scores between both groups**

197 All residents passed the training test; however, the mean scores of the residents were
198 higher in the ST group than in the CT group (8.74 ± 1.09 vs 8.13 ± 1.31 , $P = 0.014$). After

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4 199 the clinical training, the training satisfaction rates of all residents were similar (97.87%
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6 200 vs 91.67%, $P>0.05$); however, when asked whether they wished to participate in the
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9 201 training again, the residents in the ST group showed a higher willingness rate than
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11 202 residents in the CT groups (93.62% vs 79.17%, $P=0.04$).

203 **The performance of arterial puncture in residents**

204 After the training, all residents underwent an arterial puncture test (Table 2), and the
205 success rate of the procedure was higher in the ST group than in the CT group (78.72%
206 vs 58.33%, $P=0.033$); however, the total puncture success rate was similar between the
207 two groups (95.74% vs 91.67%, $P>0.05$). The complications of the puncture sites
208 included bruising, hematoma, infection and pseudoaneurysm, and there was no
209 significant difference in the incidence of complications between the ST and CT groups
210 (17.02% vs 18.75%, $P>0.05$); however, the time of the puncture procedure was shorter
211 in the ST group than in the CT group (9.56 ± 5.24 min vs 12.15 ± 6.87 min, $P=0.002$), and
212 the comfort score of patients was higher in the ST group than in the CT group according
213 to the NRS scores (5.49 ± 1.72 vs 4.71 ± 1.57 , $P=0.023$).

214 **The outcome of cerebrovascular angiography**

215 All residents needed to complete the final cerebrovascular angiography test; the related
216 parameters are listed in Table 3. The residents in the ST group showed a shorter study
217 curve with a lower mean LTP than residents in the CT groups (3.65 mon vs 4.07 mon,
218 $P<0.01$), and the TCP of the final test was higher in the CT group than in the ST group
219 (41.32 min vs 33.81 min, $P=0.002$). The radiation damage-related parameters were
220 recorded, and the residents in the CT group showed higher mean values of FTP (631.47

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4 221 s vs 489.33 s, $P<0.001$) and CAK than the residents in the ST group (463.16 vs 401.30
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6 222 mGy, $P=0.043$); however, the mean DAP value in both groups indicated no difference
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9 223 (128624.30 mGy.cm² vs 128012.10 mGy.cm², $P>0.052$).

224 **DISCUSSION**

225 The development of vascular surgery occurred relatively late in China; thus, the training
226 model used for vascular residents in most university hospitals was traditional training;
227 however, traditional training did not improve residents' understanding and interest in
228 vascular surgery. In past decades, there were fewer residents who chose vascular
229 surgery as a career option in China, which was consistent with the reports of previous
230 studies [7]. Therefore, improving residents' interest in vascular surgery and promoting
231 vascular clinical performance have been the main problems associated with clinical
232 training [8]. Earlier studies have shown that compared with traditional training, the use
233 of network media, social media and simulation systems can achieve better training
234 results [9-11]. In this study, we used the vascular simulation system to assist residents in
235 clinical training. The results revealed that simulation training could significantly
236 improve the clinical practice effect of residents. The residents who received the
237 simulation training had significantly higher theoretical scores; in addition, the interest
238 level of residents was higher after simulation training. The vascular simulation system
239 could standardize complex vascular systems and different vascular lesions through
240 analog calculations, which could help residents practice vascular skills training earlier
241 and improve the interest and performance of residents [3]. Our result reveals that the
242 residents could deeply understand theoretical knowledge and practical knowledge

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4 243 through simulation training, which also helps to improve the residents' theoretical and
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6 244 practical knowledge.
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9 245 After simulation training and basic training, residents need further vascular operation
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11 246 training under the guidance of tutors, and the basic procedure for vascular residents is
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14 247 arterial puncture. However, it is impossible for residents to repeatedly perform the
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17 248 procedure during the treatment of patients; thus, in vitro simulation training has become
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20 249 the main teaching method in the training of vascular residents. Residents who received
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22 250 simulator training showed better clinical performance in the vascular surgery rotation,
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25 251 more motivation to learn, a shorter learning time and a lower number of clinical
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27 252 procedural errors, and the patients indicated a lower discomfort rate with the procedure
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30 253 [12, 13]. In our study, the results confirmed that the residents who underwent the
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32 254 simulation training had a significantly higher success rate of arterial puncture, and the
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35 255 time of the puncture procedure was also significantly lower. Each step of the vascular
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37 256 procedure could be programmed and standardized in the simulation system. After the
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40 257 teacher's explanation and auxiliary training, it was easier for residents to develop
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43 258 standardized vascular skill habits and the correct procedural process. Finally, we
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46 259 evaluated the training effect with the cerebrovascular angiography procedure. Our
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48 260 results proved that the learning time of the angiography procedure and time of
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51 261 completed procedures were significantly lower in residents with simulation training;
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53 262 these results were consistent with previous reports [14]. This finding also confirmed that
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56 263 different simulation systems and teaching models could improve the effectiveness of
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59 264 clinical teaching and promote the understanding and proficiency of vascular practical
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4 265 performance.

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6 266 Furthermore, the final effect of clinical training should be assessed by the practice
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9 267 procedure of residents. Our study confirmed that vascular simulation training could
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11 268 promote the practice knowledge of residents and promote the understanding of vascular
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14 269 surgical procedure. Most cases of vascular disease teaching need to be performed under
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17 270 radiation; thus, simulation training could avoid radiation damage to teachers, patients
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20 271 and residents. In this study, the results demonstrated that simulation training could
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22 272 decrease the fluo time and cumulative air kerma of the procedure, which meant that
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25 273 simulation training could reduce the radiation damage of patients and residents, and
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28 274 radiation protection was an important teaching ethics component in vascular surgery
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31 275 practice. However, due to the limitations of our teaching funding and the time course,
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33 276 only selective residents underwent the simulation training for 2 weeks, which was
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36 277 different from what occurs in advanced vascular centers. Other reports have shown that
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38 278 simulation training for 8 weeks can improve the procedure skills of residents, contribute
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41 279 to patient safety and have a positive impact on the career planning and choice of
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44 280 vascular surgeons [15]. Therefore, the simulation training should be the basic course for
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46
47 281 residents. Therefore, the simulation training should be the basic course for residents,
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50 282 especially in pre-career students and residents in rotation, meanwhile the simulation
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53 283 training should be well-defined and step-planned, otherwise, the simulation training
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56 284 may result in an impaired learning and worse performance in real clinical practice [16].

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59 285 **Limitations**

60 286 There were several limitations. First, this study was not a prospective randomized study,

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4 287 and the conclusions of this study should be confirmed in the future; Second, when
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6 288 compared with Western countries, the simulation training is not wildly used in China,
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9 289 thus the truly effect of the simulation training is not investigated deeply; Third, the
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12 290 clinical performance of the residents should be evaluated via the real clinical procedure
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14 291 after the simulation training, this is the next step of our study.

17 292 **Conclusions**

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19 293 Our results confirmed that a vascular simulation system could improve the clinical
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22 294 skills of residents and reduce the radiation damage received by patients and residents in
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25 295 endovascular procedures.

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27 296 **Author Contributions:** LY, YZ L: data collection. LY, YZ L, JL L and YM L:
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30 297 conception or design of the work; data analysis and interpretation; critical revision of
31
32
33 298 the article; drafting of the article and final approval of the version to be published.

34
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37
38 300 Experts (AJE).

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40 301 **Funding:** This project was supported by the Natural Science Foundation of China
41
42
43 302 (NO.8197 0365)

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45 303 **Conflicts of Interest:** None.

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48 304 **Patient consent for publication:** Not required.

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50 305 **Ethical approval:** This study was approved by the institutional review and ethics board
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53 306 of the First Affiliated Hospital of Xi'an Jiaotong University.

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55 307 **Data availability statement:** Data are available upon reasonable request.

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6 354 **Figure legends**
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9 355 **Figure 1.** The vascular simulator system (Angiomentor system, Simbionix, Ltd.,
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11 356 Cleveland, OH) used in this study simulated the vascular interventional procedures: a)
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14 357 work station; b) pedal; c) simulator.
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For peer review only

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376 **Tables**377 **Table 1 The baseline data of both groups**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Sex (M)	44 (91.67)	42 (89.36)	0.70
Age (years)	33.13±3.04	33.91±4.94	0.35
Academic degree			0.36
bachelor	22 (45.83)	26 (55.32)	
postgraduate	26 (54.17)	21 (44.68)	
Specialty background			0.48
vascular	30 (62.50)	26 (55.32)	
nonvascular	18 (37.50)	21 (44.68)	
Work experience			0.35
> 3 years	16 (33.33)	20 (42.55)	
≤ 3 years	32 (66.67)	27 (57.45)	

378 CT: conventional training; ST: simulation training; M: male.

379 *P* value, compared with the CT group

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386 **Table 2 The performance of arterial puncture in residents**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Puncture success rate	28 (58.33)	37 (78.72)	0.033
Total puncture success rate	44 (91.67)	45 (95.74)	0.69
Complications from puncture	9 (18.75)	8 (17.02)	0.83
bruising	5 (10.42)	6 (12.77)	
hematoma	3 (6.25)	2 (4.26)	
infection	0	0	
arteriovenous fistula	0	0	
pseudoaneurysm	1 (2.08)	0	
time of puncture (min)	12.15±6.87	9.56±5.24	0.002
Comfort score of patients	4.71±1.57	5.49±1.72	0.023

387 CT: conventional training; ST: simulation training.

388 *P* value, compared with the CT group

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397 **Table 3 The performance on cerebrovascular angiography in residents**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
LTP (mon)	4.07±0.77	3.65±0.64	<0.01
TCP (min)	41.32±12.56	33.81±10.11	0.002
FTP (s)	631.47±243.65	489.33±237.13	0.005
CAK (mGy)	463.16±134.14	401.30±149.06	0.043
DAP (mGy.cm ²)	128624.30±28982.22	128012.10±31035.08	0.92

398 CT: conventional training; ST: simulation training; LTP: learn time to complete

399 procedure from beginning; TCP: time of complete procedure at the final test; FTP: fluo

400 time of procedure; CAK: cumulative air kerma; DAP: dose area product

401 *P* value, compared with the CT group

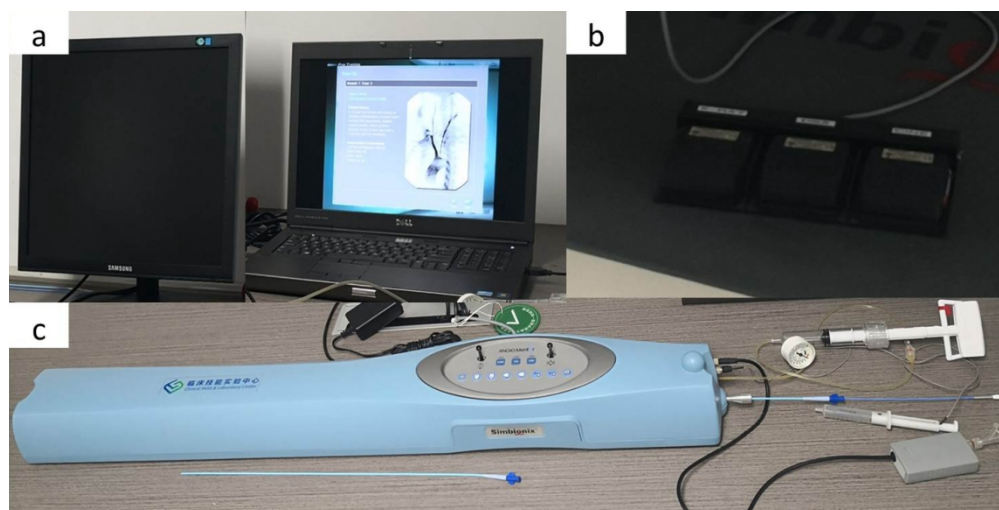


Figure 1. The vascular simulator system (Angiomentor system, Symbionix, Ltd., Cleveland, OH) used in this study simulated the vascular interventional procedures: a) work station; b) pedal; c) simulator.

124x63mm (300 x 300 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1–2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1–2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3–4
Objectives	3	State specific objectives, including any pre-specified hypotheses	3–4
Methods			
Study design	4	Present key elements of study design early in the paper	4–6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4–6
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4–6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	4–6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4–6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4–6
Bias	9	Describe any efforts to address potential sources of bias	4–6
Study size	10	Explain how the study size was arrived at	4–6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4–6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	7

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	7
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7–9
		(b) Give reasons for non-participation at each stage	7–9
		(c) Consider use of a flow diagram	7–9
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7–9
		(b) Indicate number of participants with missing data for each variable of interest	7–9
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	7–9
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7–9
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	7–9
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	7–9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7–9
		(b) Report category boundaries when continuous variables were categorized	7–9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7–9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7–9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9–11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9–11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9–11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9–11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

The effect of vascular simulation training on practice performance in residents: a retrospective cohort study

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Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Medical education and training, Surgery
Keywords:	Vascular surgery < SURGERY, MEDICAL EDUCATION & TRAINING, VASCULAR MEDICINE

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4 1 **The effect of vascular simulation training on practice**
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6 2 **performance in residents: a retrospective cohort study**
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38 14 **Running head:** Effect of ST in residents
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4 23 **Abstract**

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6 24 **Objective:** This study aims to investigate the teaching effect of vascular simulation
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9 25 training in rotating vascular residents.

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12 26 **Design:** Retrospective cohort study

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14 27 **Setting and participants:** A total of 95 vascular residents were included from 2015 to
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17 28 2018 in a university affiliated center western China, and divided into a simulation
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19 29 training (ST) group and a conventional training (CT) group. ST group received
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22 30 simulation training and conventional training, and the CT group only received
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25 31 conventional training.

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27 32 **Primary outcome measures:** Theoretical scores were assessed, and the technique
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30 33 parameters, complications and radiation damage of the procedures were analyzed.

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32 34 **Results:** The mean scores (8.74 ± 1.09 vs 8.13 ± 1.31) and the rate of willingness for
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35 35 retraining (93.62% vs 79.17%) in residents were higher in the ST group than in the CT
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38 36 group ($P < 0.05$). The success rate of arterial puncture was significantly higher in the ST
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41 37 group (78.72% vs 58.33% , $P = 0.03$); however, the incidence of complications was
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44 38 similar between the two groups ($P > 0.05$). The time of the puncture procedure was
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47 39 significantly lower (9.56 ± 5.24 min vs 12.15 ± 6.87 min), and the comfort score of the
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50 40 patient (5.49 ± 1.72 vs 4.71 ± 1.57) was higher in the ST group than in the CT group
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53 41 ($P < 0.05$). At the end of the assessment, the learning time for angiography (3.65 ± 0.64
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56 42 min vs 4.07 ± 0.77 min) and the complete procedure time (33.81 ± 10.11 min vs
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59 43 41.32 ± 12.56 min) were lower in the ST group than in the CT group ($P < 0.01$). The fluo
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44 time for angiography (489.33 ± 237.13 s vs 631.47 ± 243.65 s) and the cumulative air

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4 45 kerma (401.30 ± 149.06 mGy vs 461.16 ± 134.14 mGy) were significantly decreased in
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7 46 ST group ($P < 0.05$).

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9 47 **Conclusion:** The application of a vascular simulation system can significantly improve
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12 48 the clinical performance of residents and reduce the radiation damage from a single
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15 49 intervention procedure in patients.

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17 50 **Keywords:** Vascular surgery; Medical education & training; Teaching modes;
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20 51 Simulation training; Traditional teaching
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67 **Article summary**

68 **Strengths and limitations of this study**

- 69 ◆ The simulation training could promote the mean scores of residents
- 70 ◆ The simulation training could improve the clinical performance of residents
- 71 ◆ The simulation training could reduce the radiation damage
- 72 ◆ The simulation training should be widely used in clinical teaching practice.
- 73 ◆ The conclusions of this study should be confirmed via prospective randomized
- 74 study.

89 INTRODUCTION

90 In recent years, with changes in the disease spectrum of Chinese patients, the incidence
91 of peripheral arterial disease has increased significantly, which has also caused a severe
92 economic and social burden [1]. Therefore, it is becoming increasingly important to
93 strengthen general and specialized vascular disease skills education in the training of
94 medical residents [2, 3]. In the past decade, the practical skills training of resident has
95 been mainly carried out through conventional teaching (CT) modes (including
96 classroom teaching, lectures and surgical practice), and residents lack sufficient
97 practical procedures with simulation training from theoretical knowledge to practical
98 procedures, therefore, the true teaching effect was not ideal.

99 Three-dimensional vascular simulator systems (Angiomentor system, Symbionix, Ltd.,
100 Cleveland, OH) use digital simulation to quantify the vascular interventional procedures
101 of the cardiovascular, peripheral and cerebrovascular systems. Residents can use the
102 system to select cases for simulation training; ultimately, the simulation training results
103 are scored according to the operating steps of the system. This simulation training can
104 promote the mastery of vascular procedure performance in residents [4-6], and this
105 system provides an opportunity to perform endovascular procedures in a safe
106 environment as an educational tool for novice residents.

107 However, due to the late entry of simulation systems in China, there has been no
108 report of the use of 3-dimensional vascular simulation systems in clinical practice
109 teaching in the area of vascular surgery. Therefore, we have retrospectively collected
110 the teaching data of residents who received the simulation training and those who did

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4 111 not in our hospital. The aim of this study was to assess the effect of simulation-based
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6 112 training on improving the technical performance and subsequent clinical procedures of
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9 113 residents in vascular surgery.

114 **METHODS**

115 **Study procedures**

116 A total of 95 vascular resident trainees at the First Affiliated Hospital of Xi'an Jiaotong
117 University were respectively collected in this study from Jan 2015 to Dec 2018, 47
118 vascular residents received simulation-based vascular training (ST group) for two weeks,
119 and then they completed the last clinical training. The other 48 residents only completed
120 conventional clinical training (CT group, including classroom teaching, lectures and
121 surgical practice) without the simulation course, and all residents needed to complete 6
122 months of endovascular training in vascular surgery. A survey was administered to
123 determine the demographics, academic degree, specialty level, and previous work
124 experiences that may have been relevant in terms of the residents' ability to learn
125 vascular interventional skills. This study was approved by the institutional review and
126 ethics board of the First Affiliated Hospital of Xi'an Jiaotong University
127 (XJTU1AF2014LSK-112), all of the patients provided written informed consent.

128 Before the course was performed, the residents in the ST group received a
129 standardized introduction to the endovascular simulator and performed a
130 cerebrovascular angiography procedure. The 2-week curriculum consisted of theory
131 teaching and 30-60 min lectures per day covering basic catheter-based interventions,
132 cerebrovascular disease, superficial femoral artery disease and renal artery disease. The

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4 133 residents received 1-hour mentored simulator sessions per day and practiced carotid,
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6 134 renal and superficial femoral artery interventions. This course was performed by a tutor.
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9 135 Then, residents needed to complete the primary endovascular procedure with direct
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11 136 instruction. During the entire training process, each resident was required to complete
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13
14 137 the simulation training for no less than 1 hour per day. The course concluded with a
15
16
17 138 final cerebrovascular angiography procedure performed on the simulator. The residents
18
19 139 in the CT group underwent the basic 2-week curriculum consisting of theory teaching
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22 140 and 30-60 min lectures per day covering basic endovascular intervention procedures but
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25 141 without the simulation training course.

26 27 142 **Simulation system**

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30 143 The vascular simulator system (Angiomentor system, Symbionix, Ltd., Cleveland, OH,
31
32 144 Fig 1) was composed of a standard desktop computer with software that simulated the
33
34
35 145 human arterial system in 3 dimensions, and any user could perform the endovascular
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37
38 146 interventional procedures under the instruction of the system. This simulation system
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40
41 147 was connected to a haptic pressure feedback module, which used a force feedback
42
43 148 system to detect external devices. When the users inserted the angiography catheters
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46 149 and wires, injected contrast and performed the endovascular procedures with digital
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48
49 150 subtraction angiography, all procedures could then be displayed on the screen in real
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51
52 151 time. The user was able to select the device to be simulated through one monitor, and
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54 152 the second monitor was used to display the simulated fluoroscopic image.

55 56 153 **Procedure evaluation**

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58 154 When the residents completed the training course, all residents received assessments of
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4 155 theoretical knowledge at 1 month and practical assessments at 6 months. The teaching
5
6 156 expert group made the theoretical test questions based on the key points of vascular
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9 157 disease as well as the endovascular interventional procedures and technical points
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11
12 158 involved in vascular surgery clinical training (the theoretical knowledge test is
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14 159 formulated according to the standardized question bank and the simulation system
15
16
17 160 question bank), and then the residents completed the assessment independently. Finally,
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19
20 161 the expert group determined the student's score based on the results of the test
21
22 162 (including the detailed information of knowledge and practice). The theoretical score
23
24 163 range was 0-10, and a passing score was defined as a score higher than 7. All residents
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27 164 completed the arterial puncture procedure with the Seldinger technique and performed
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29
30 165 the cerebrovascular angiography procedure. The success criterion of arterial puncture
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33 166 was defined as follows: all puncture procedures were successfully completed, and the
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35 167 sheath was successfully inserted into the femoral artery. If the residents failed to
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37
38 168 complete the processes of puncture and sheath placement, which was defined as a
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41 169 puncture failure, then the puncture was performed by the teacher. The puncture success
42
43 170 rate, puncture time and complications were recorded, and the comfort scores of the
44
45
46 171 patients during the puncture procedure were assessed with a numerical rating scale
47
48 172 (NRS). The NRS score ranged from 0 to 10, where 0 indicates worst uncomfortable
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50
51 173 pain and 10 indicates comfortable pain [7]. Subsequently, the residents needed to
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54 174 complete the cerebrovascular angiography procedure. The evaluation indicators of
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56 175 angiography were as following: learn time to complete the procedure (LTP, defined as
57
58 176 the time from the beginning of training to the completion of the first angiography
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4 177 independently), time of complete procedure at the final test (TCP), fluo time of
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6 178 procedure (FTP), cumulative air kerma (CAK) and dose area product (DAP). TCP, FTP,
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9 179 CAK and DAP were defined as the time of procedure and related parameters of the
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11
12 180 assessed angiography procedure at the end of the training.

14 181 **Patient and public involvement**

16
17 182 Patients and the public were not involved in the design or planning of the study.

19 183 **Statistical Analysis**

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22 184 All data were analyzed using SPSS v. 11.0 (SPSS, Chicago, IL, USA), and $P < .05$ was
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24
25 185 considered statistically significant. To test the difference between groups, we used
26
27 186 Chi-square analysis for categorical variables and Student's t-tests for continuous
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29
30 187 variables, and we tested the significance of the difference between 2 independent
31
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33 188 proportions when the results were presented as percentages.

35 189 **RESULTS**

37 190 **The baseline data of the two groups**

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40 191 This study included 48 residents and 47 residents who were retrospectively recruited in
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42
43 192 this study, and there was no significant difference in baseline data between the two
44
45 193 groups (Table 1, $P > 0.05$). There were 44 males and 4 females who received CT training,
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48 194 with a mean age of 33.13 years, and 42 males and 5 females who received ST training,
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50
51 195 with a mean age of 33.91 years ($P > 0.05$). The background academic degrees were
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53 196 bachelor and postgraduate degrees in the CT and ST groups ($P > 0.05$), and 30 and 26
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56 197 residents had a specialty background in vascular surgery in both groups (62.50% vs
57
58 198 55.32%, $P > 0.05$). The clinical work experience of most residents was less than three
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199 years in both groups (66.67% vs 57.45, $P>0.05$).

200 **The theoretical scores between both groups**

201 All residents passed the training test; however, the mean scores of the residents were
202 higher in the ST group than in the CT group (8.74 ± 1.09 vs 8.13 ± 1.31 , $P=0.014$). After
203 the clinical training, the training satisfaction rates of all residents were similar (97.87%
204 vs 91.67%, $P>0.05$); however, when asked whether they wished to participate in the
205 training again, the residents in the ST group showed a higher willingness rate than
206 residents in the CT groups (93.62% vs 79.17%, $P=0.04$).

207 **The performance of arterial puncture in residents**

208 After the training, all residents underwent an arterial puncture test (Table 2), and the
209 success rate of the procedure was higher in the ST group than in the CT group (78.72%
210 vs 58.33%, $P=0.033$); however, the total puncture success rate was similar between the
211 two groups (95.74% vs 91.67%, $P>0.05$). The complications of the puncture sites
212 included bruising, hematoma, infection and pseudoaneurysm, and there was no
213 significant difference in the incidence of complications between the ST and CT groups
214 (17.02% vs 18.75%, $P>0.05$); however, the time of the puncture procedure was shorter
215 in the ST group than in the CT group (9.56 ± 5.24 min vs 12.15 ± 6.87 min, $P=0.002$), and
216 the comfort score of patients was higher in the ST group than in the CT group according
217 to the NRS scores (5.49 ± 1.72 vs 4.71 ± 1.57 , $P=0.023$).

218 **The outcome of cerebrovascular angiography**

219 All residents needed to complete the final cerebrovascular angiography test; the related
220 parameters are listed in Table 3. The residents in the ST group showed a shorter study

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4 221 curve with a lower mean LTP than residents in the CT groups (3.65 mon vs 4.07 mon,
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6 222 $P<0.01$), and the TCP of the final test was higher in the CT group than in the ST group
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9 223 (41.32 min vs 33.81 min, $P=0.002$). The radiation damage-related parameters were
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11 224 recorded, and the residents in the CT group showed higher mean values of FTP (631.47
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14 225 s vs 489.33 s, $P<0.001$) and CAK than the residents in the ST group (463.16 vs 401.30
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17 226 mGy, $P=0.043$); however, the mean DAP value in both groups indicated no difference
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19 227 (128624.30 mGy.cm² vs 128012.10 mGy.cm², $P>0.052$).

228 **DISCUSSION**

229 The development of vascular surgery occurred relatively late in China; thus, the training
230 model used for vascular residents in most university hospitals was traditional training;
231 however, traditional training did not improve residents' understanding and interest in
232 vascular surgery. In past decades, there were fewer residents who chose vascular
233 surgery as a career option in China, which was consistent with the reports of previous
234 studies [7]. Therefore, improving residents' interest in vascular surgery and promoting
235 vascular clinical performance have been the main problems associated with clinical
236 training [8]. Earlier studies have shown that compared with traditional training, the use
237 of network media, social media and simulation systems can achieve better training
238 results [9-11]. In this study, we used the vascular simulation system to assist residents in
239 clinical training. The results revealed that simulation training could significantly
240 improve the clinical practice effect of residents. The residents who received the
241 simulation training had significantly higher theoretical scores; in addition, the interest
242 level of residents was higher after simulation training. The vascular simulation system

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4 243 could standardize complex vascular systems and different vascular lesions through
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6 244 analog calculations, which could help residents practice vascular skills training earlier
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9 245 and improve the interest and performance of residents [3]. Our result reveals that the
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11 246 residents could deeply understand theoretical knowledge and practical knowledge
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14 247 through simulation training, which also helps to improve the residents' theoretical and
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17 248 practical knowledge.

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19 249 After simulation training and basic training, residents need further vascular operation
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22 250 training under the guidance of tutors, and the basic procedure for vascular residents is
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25 251 arterial puncture. However, it is impossible for residents to repeatedly perform the
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28 252 procedure during the treatment of patients; thus, in vitro simulation training has become
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31 253 the main teaching method in the training of vascular residents. Residents who received
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34 254 simulator training showed better clinical performance in the vascular surgery rotation,
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37 255 more motivation to learn, a shorter learning time and a lower number of clinical
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40 256 procedural errors, and the patients indicated a lower discomfort rate with the procedure
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43 257 [12, 13]. In our study, the results confirmed that the residents who underwent the
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46 258 simulation training had a significantly higher success rate of arterial puncture, and the
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49 259 time of the puncture procedure was also significantly lower. Each step of the vascular
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52 260 procedure could be programmed and standardized in the simulation system. After the
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55 261 teacher's explanation and auxiliary training, it was easier for residents to develop
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58 262 standardized vascular skill habits and the correct procedural process. Finally, we
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60 263 evaluated the training effect with the cerebrovascular angiography procedure. Our
60 264 results proved that the learning time of the angiography procedure and time of

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4 265 completed procedures were significantly lower in residents with simulation training;
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6 266 these results were consistent with previous reports [14]. This finding also confirmed that
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9 267 different simulation systems and teaching models could improve the effectiveness of
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11 268 clinical teaching and promote the understanding and proficiency of vascular practical
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14 269 performance.

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17 270 Furthermore, the final effect of clinical training should be assessed by the practice
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19 271 procedure of residents. Our study confirmed that vascular simulation training could
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22 272 promote the practice knowledge of residents and promote the understanding of vascular
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25 273 surgical procedure. Most cases of vascular disease teaching need to be performed under
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27 274 radiation; thus, simulation training could avoid radiation damage to teachers, patients
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30 275 and residents. In this study, the results demonstrated that simulation training could
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33 276 decrease the fluo time and cumulative air kerma of the procedure, which meant that
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36 277 simulation training could reduce the radiation damage of patients and residents, and
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38 278 radiation protection was an important teaching ethics component in vascular surgery
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40 279 practice. However, due to the limitations of our teaching funding and the time course,
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43 280 only selective residents underwent the simulation training for 2 weeks, which was
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46 281 different from what occurs in advanced vascular centers. Other reports have shown that
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48 282 simulation training for 8 weeks can improve the procedure skills of residents, contribute
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51 283 to patient safety and have a positive impact on the career planning and choice of
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54 284 vascular surgeons [15]. Therefore, the simulation training should be the basic course for
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56 285 residents. Therefore, the simulation training should be the basic course for residents,
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59 286 especially in pre-career students and residents in rotation, meanwhile the simulation
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4 287 training should be well-defined and step-planned, otherwise, the simulation training
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6 288 may result in an impaired learning and worse performance in real clinical practice [16].
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9 289 **Limitations**

10
11 290 There were several limitations. First, this study was not a prospective randomized study,
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14 291 and the conclusions of this study should be confirmed in the future; Second, when
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17 292 compared with Western counties, the simulation training is not widely used in China,
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19 293 thus the truly effect of the simulation training is not investigated deeply; Third, the
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22 294 clinical performance of the residents should be evaluated via the real clinical procedure
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25 295 after the simulation training, this is the next step of our study.
26

27 296 **Conclusions**

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30 297 Our results confirmed that a vascular simulation system could improve the clinical
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32 298 skills of residents and reduce the radiation damage received by patients and residents in
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35 299 endovascular procedures.
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37
38 300 **Author Contributions:** LY, YZ L: data collection. LY, YZ L, JL L and YM L:
39
40 301 conception or design of the work; data analysis and interpretation; critical revision of
41
42
43 302 the article; drafting of the article and final approval of the version to be published.
44

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46
47
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49
50
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52
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54

55
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57
58 308 (NO.8197 0365)
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4 309 **Conflicts of Interest:** None.
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6 310 **Patient consent for publication:** Not required.
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9 311 **Ethical approval:** This study was approved by the institutional review and ethics board
10
11 of the First Affiliated Hospital of Xi'an Jiaotong University.
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14 313 **Data availability statement:** Data are available upon reasonable request.
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6 376 **Figure legends**
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9 377 **Figure 1.** The vascular simulator system (Angiomentor system, Simbionix, Ltd.,
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11 378 Cleveland, OH) used in this study simulated the vascular interventional procedures: a)
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14 379 work station; b) pedal; c) simulator.
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For peer review only

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398 **Tables**399 **Table 1 The baseline data of both groups**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Sex (M)	44 (91.67)	42 (89.36)	0.70
Age (years)	33.13±3.04	33.91±4.94	0.35
Academic degree			0.36
bachelor	22 (45.83)	26 (55.32)	
postgraduate	26 (54.17)	21 (44.68)	
Specialty background			0.48
vascular	30 (62.50)	26 (55.32)	
nonvascular	18 (37.50)	21 (44.68)	
Work experience			0.35
> 3 years	16 (33.33)	20 (42.55)	
≤ 3 years	32 (66.67)	27 (57.45)	

400 CT: conventional training; ST: simulation training; M: male.

401 *P* value, compared with the CT group

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408 **Table 2 The performance of arterial puncture in residents**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
Puncture success rate	28 (58.33)	37 (78.72)	0.033
Total puncture success rate	44 (91.67)	45 (95.74)	0.69
Complications from puncture	9 (18.75)	8 (17.02)	0.83
bruising	5 (10.42)	6 (12.77)	
hematoma	3 (6.25)	2 (4.26)	
infection	0	0	
arteriovenous fistula	0	0	
pseudoaneurysm	1 (2.08)	0	
time of puncture (min)	12.15±6.87	9.56±5.24	0.002
Comfort score of patients	4.71±1.57	5.49±1.72	0.023

409 CT: conventional training; ST: simulation training.

410 *P* value, compared with the CT group

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419 **Table 3 The performance on cerebrovascular angiography in residents**

	CT group (n=48)	ST group (n=47)	<i>P</i> value
LTP (mon)	4.07±0.77	3.65±0.64	<0.01
TCP (min)	41.32±12.56	33.81±10.11	0.002
FTP (s)	631.47±243.65	489.33±237.13	0.005
CAK (mGy)	463.16±134.14	401.30±149.06	0.043
DAP (mGy.cm ²)	128624.30±28982.22	128012.10±31035.08	0.92

420 CT: conventional training; ST: simulation training; LTP: learn time to complete

421 procedure from beginning; TCP: time of complete procedure at the final test; FTP: fluo

422 time of procedure; CAK: cumulative air kerma; DAP: dose area product

423 *P* value, compared with the CT group

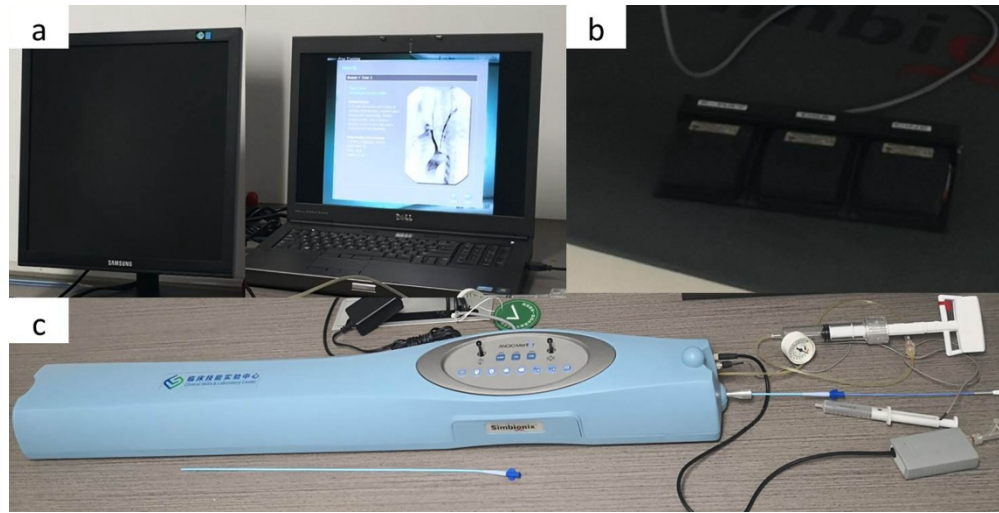


Figure 1. The vascular simulator system (Angiomentor system, Simbionix, Ltd., Cleveland, OH) used in this study simulated the vascular interventional procedures: a) work station; b) pedal; c) simulator.

124x63mm (500 x 500 DPI)

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1–2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1–2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3–4
Objectives	3	State specific objectives, including any pre-specified hypotheses	3–4
Methods			
Study design	4	Present key elements of study design early in the paper	4–6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4–6
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4–6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	4–6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4–6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4–6
Bias	9	Describe any efforts to address potential sources of bias	4–6
Study size	10	Explain how the study size was arrived at	4–6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4–6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	7
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	7

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	7
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7–9
		(b) Give reasons for non-participation at each stage	7–9
		(c) Consider use of a flow diagram	7–9
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7–9
		(b) Indicate number of participants with missing data for each variable of interest	7–9
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	7–9
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7–9
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	7–9
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	7–9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7–9
		(b) Report category boundaries when continuous variables were categorized	7–9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7–9
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7–9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9–11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9–11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9–11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9–11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.