

Clinical Usefulness of the 3.3Fr Catheter for Cerebral Angiography

Shinya KOHYAMA Ikuo OCHIAI Nahoko UEMIYA Tomoyuki YOSHIHARA Fumitaka YAMANE
Ryuzaburo KANAZAWA Hiroaki NEKI Hidetoshi SHIMAGUCHI Hideaki ISHIHARA Shoichiro ISHIHARA

Division of Endovascular Neurosurgery, Stroke Center, International Medical Center, Saitama Medical University

●Abstract●

Objectives: Although use of the small-sized catheters is less invasive for cerebral angiography (CA), difficult manipulability for tortuous vessels is a limitation. We report the clinical feasibility of a newly developed 3.3Fr catheter for CA in terms of manipulability.

Methods: The data of 80 consecutive patients who underwent CA via the femoral or radial arteries using the newly developed 3.3Fr catheter were analyzed retrospectively. The duration of the CA procedure and fluoroscopy procedure in patients who underwent CA using a 3.3Fr catheter were compared with those in patients who underwent CA using a 4Fr catheter. We also analyzed the data of 14 patients who underwent CA with the new 3.3Fr catheter and had previously undergone CA with a 4Fr catheter using the same procedures including access routes and selected vessels.

Results: CA was completed in all patients without any complications using the 3.3Fr catheter. The differences in the durations of CA and fluoroscopy were not statistically significant between the 3.3Fr and 4Fr catheter groups. There was also no significant difference in CA outcome in the 14 patients who underwent the same procedure using different sized catheters.

Conclusions: The newly developed 3.3Fr catheter is useful for CA and its manipulability is the same as that of the 4Fr catheter.

●Key Words●

cerebral angiography, 3.3Fr catheter, transradial approach

< Correspondence Address: Shinya KOHYAMA, 1397-1 Yamane, Hidaka, Saitama, 350-1298, Japan
E-mail: skohyama@saitama-med.ac.jp >

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Introduction

Catheterized cerebral angiography (CA) remains the gold standard for examining the cerebral vasculature, although magnetic resonance angiography (MRA) and three-dimensional computed tomographic angiography (CTA) are preferred because they are less invasive. It is important to reduce the burden of patients undergoing CA. With the development of neuroendovascular therapy, CA has become more important for interventional planning and follow-up of cerebrovascular disease. Komiyama et al. and Kiyosue et al. reported the usefulness of small catheter systems to lower the risk of complications and showed that smaller catheter size reduced the time of bed rest and risk of bleeding at the

puncture site after the procedure^{7,9)}. However, the small catheter systems have not been used widely because of low kink resistance and problems with manipulation. Recently the new 3.3Fr catheter (Medikit, Tokyo, Japan) designed with a tightly wound single-wire blade and softer nylon outer tubing was developed for better trackability and kink resistance⁸⁾. In this report, we evaluate the clinical feasibility of the 3.3Fr catheter in terms of manipulability.

Patients and Methods

Between November 2010 and January 2011, the newly developed 3.3Fr catheter was used at our institute for scheduled CA in 80 consecutive patients. The 3.3Fr catheter was not used in patients undergoing emergency

or preprocedural CA because the subsequent interventional procedures using larger catheters would negate the benefit of smaller punctures produced by smaller catheters. A transfemoral approach was used in all patients in the first CA, in order to check the access route for possible endovascular therapy. A transradial approach was recommended for patients who had a follow-up CA after treatment and a positive modified Allen's test. Data from the 80 patients were analyzed retrospectively and compared with data from an equal number of patients who had a scheduled CA between August 2010 and October 2010 with a 4Fr catheter, the standard size used in our institute. We also compared the data of 14 patients who underwent CA with a 3.3Fr catheter and had previously undergone the procedure with a 4Fr catheter; the same access routes and selected vessels were used in both procedures in these patients. Informed consent for CA was obtained from all patients. The study protocol was approved by the institutional review board of our institute.

In contrast to the double-wired blade design of the existing 3.3Fr catheter, the newly developed 3.3Fr catheter has a tightly wound single-wire blade and an outer tube made of extra soft nylon. The new 3.3Fr catheter was used with a 30 cm, 3Fr sheath and a 0.032-inch guidewire, whereas the 4Fr catheter was used with a 25 cm, 4Fr sheath and a 0.035-inch guidewire. All devices were manufactured by Medikit. The shapes of the catheters used were Headhunter, John-Benson, and Simmons for the transfemoral approach, and Modified-Simmons type 2 and type 4 for the transradial

approach¹¹⁾. CA was performed under local anesthesia on a biplane flat panel digital subtraction angiography (DSA) unit (Allura Xper 20/10; Philips Medical Systems, Best, the Netherlands). When the first CA was performed without information from MR or CT angiography on the aortic arch and branches of the thoracic aorta (such as the innominate, subclavian, vertebral, and common carotid arteries), a Headhunter or John-Benson type catheter was used for aortography with 14 mL of nonionic contrast medium delivered at a rate of 7 mL/s via the 3.3Fr catheter or with 20 mL of medium delivered at a rate of 11 mL/s via the 4Fr catheter. Heparin was added to the contrast medium (1000 IU/100 mL) and normal saline used for flushing the catheters (2500 IU/500 mL); however, heparin was not directly administered systemically. Of the six operators, three (S. K., F. M., and R. K.) were board-certified neuroendovascular therapists, whereas three (T. Y., N. U., and I. O.) were not, but had 2, 3, and 6 years of experience in CA, respectively.

The CA data were acquired from electronic medical charts at our institution. The duration of the CA procedure was defined as the time between insertion and removal of the sheath, whereas the duration of the fluoroscopy procedure was measured automatically by the DSA unit. Detailed statistical analysis was carried out using StatMate IV (Atms Corporation, Tokyo, Japan).

Results

The characteristics of the patients are summarized in Table 1. The mean age of the patients who underwent CA using the 3.3Fr catheter was 58.5 years (range, 19–77

Table 1 Characteristics of patients

| | 3.3Fr | 4Fr |
|--|--------------|--------------|
| Total No. of patients | 80 | 80 |
| Age (y) | 58.5 (19–77) | 61.6 (14–79) |
| Sex (M/F) | 34/46 | 29/51 |
| Purpose of Angiography | | |
| Aneurysm | 50 | 58 |
| Stenosis | 15 | 11 |
| AVM | 5 | 1 |
| DAVF | 5 | 4 |
| Tumor | 7 | 6 |
| Use of antiplatelet or anticoagulant drugs | 15 | 23 |

years) and 58% of them were female. There was no statistically significant difference between the 3.3Fr and 4Fr groups in either age ($p=0.24$ using t-test), sex ($p=0.89$ using Chi-square test), or purpose of CA ($p=0.39$ using G-test with William's correction). Thirteen patients in the 3.3Fr group and eight in the 4Fr group were examined via the right radial artery (Table 2). The majority of procedures were carried out by the three non-board-certified neuroendovascular therapists. There were no significant differences in CA procedure-related variables such as approach routes used and intended arteries ($p=0.24$ and 1.0 using Pearson's chi-square test, respectively), or operators ($p=0.46$ using G-test with William's correction).

Table 2 Procedures of angiography

| | 3.3Fr | 4Fr |
|-------------------|-------|-----|
| Approach routes | | |
| transradial | 13 | 8 |
| transfemoral | 67 | 72 |
| Intended arteries | | |
| Aorta | 25 | 25 |
| Rt. CCA | 61 | 67 |
| Rt. ICA | 34 | 33 |
| Rt. ECA | 15 | 16 |
| Lt. CCA | 67 | 70 |
| Lt. ICA | 42 | 47 |
| Lt. ECA | 17 | 16 |
| Rt. VA | 16 | 19 |
| Lt. VA | 46 | 51 |
| Operators | | |
| F. Y.* | 0 | 1 |
| R. K.* | 1 | 2 |
| S. K.* | 5 | 3 |
| I. O. | 32 | 27 |
| N. U. | 22 | 17 |
| T. Y. | 20 | 30 |

* board-certified neuroendovascular therapists
 CCA: common carotid artery, ECA: external carotid artery,
 ICA: internal carotid artery, VA: vertebral artery

All planned procedures were completed in every patient without any complications. The duration of the CA procedure was 52.8 ± 21.5 min in the 3.3Fr group and 55.1 ± 22.7 min in the 4Fr group, whereas the corresponding duration of the fluoroscopy procedure was 12.3 ± 8.3 min and 12.2 ± 6.6 min, respectively (Table 3). There was no significant difference in duration of both procedures between the 3.3Fr and 4Fr groups ($p=0.52$ and 0.93 using t-test, respectively). In patients undergoing a transradial approach, the duration of the CA procedure was 39.4 ± 16.1 min in the 3.3Fr group ($n=13$) and 47.8 ± 21.0 min in the 4Fr group ($n=8$), and the duration of the fluoroscopy procedure was 12.9 ± 8.1 min in the 3.3Fr group and 16.0 ± 8.0 min in the 4Fr group. These between-group differences were not statistically significant (t-test; $p=0.31$ for CA and 0.41 for fluoroscopy). All patients undergoing CA via a transradial approach using a 3.3Fr catheter were operated on by non-board-certified neuroendovascular therapists.

In the 14 patients who underwent a similar type of CA with both a 4Fr and 3.3Fr catheter, the duration of the procedure was 37.7 ± 17.2 min with the 3.3Fr catheter and 42.7 ± 19.6 min with the 4Fr catheter, while the duration of the fluoroscopy procedure was 10.1 ± 9.1 min and 11.5 ± 11.4 min, respectively (Table 4). These differences in duration were also not statistically significant (t-test; $p=0.19$ and 0.41).

Discussion

Our data show that the duration of CA using a newly developed 3.3Fr catheter and that using a 4Fr catheter were the same, even when performed by less experienced operators. The 3.3Fr catheter was also useful for CA via the transradial approach, which is more

Table 3 Results of procedures

| | 3.3Fr | 4Fr | |
|-------------------------------|----------------------------|---------------------------|----------|
| Duration of procedure (min) | 52.8 ± 21.5 | 55.1 ± 22.7 | $p=0.52$ |
| Transradial approach | 39.4 ± 16.1 ($n=13$) | 47.8 ± 21.0 ($n=8$) | $p=0.31$ |
| Duration of fluoroscopy (min) | 12.3 ± 8.3 | 12.2 ± 6.6 | $p=0.93$ |
| Transradial approach | 12.9 ± 8.1 ($n=13$) | 16.0 ± 8.0 ($n=8$) | $p=0.41$ |
| No. of catheters used | 1.1 (1-3) | 1.1 (1-2) | |

Table 4 Duration of the procedures in patients who underwent a CA with both the 3.3Fr and 4Fr catheters

| | 3.3Fr | 4Fr | |
|-------------------------------|-------------|-------------|--------|
| Duration of procedure (min) | 37.7 ± 17.2 | 42.7 ± 19.6 | p=0.19 |
| Duration of fluoroscopy (min) | 10.1 ± 9.1 | 11.5 ± 11.4 | p=0.41 |

difficult to perform than the transfemoral approach.

Although the risk of neurological complications of CA is relatively low at 0%-2.6%, silent emboli occur in about 20% of patients^{1,5,6,14}. In addition, patients require prolonged bed rest after the procedure. The rate of access-site hematomas is also low (approximately 4%)³. Although less invasive alternative methods, such as MRA or CTA, should be utilized as first-line examinations for suspected cerebrovascular diseases, CA is now required more often for planning treatment or follow-up of disease. Less invasive CA procedures are therefore desirable.

Time to achieve hemostasis at the puncture site is thought to be shorter in Caucasians than in Asians¹³. Several reports from Western countries show the feasibility of very short bed rest time (less than 2 h) after transfemoral angiography^{2,3,4}. From this view point, the benefit of 3.3Fr catheter use may be greater for Asians than Caucasians. However, the use of the 3.3Fr catheter to further reduce bed rest time and risk of bleeding complications would be beneficial to all patients regardless of ethnicity.

Vessel obstruction at the puncture site as well as bleeding complications should also be considered in CA, especially using a transradial approach, which involves puncture of the small radial artery at the wrist^{10,12}. Nagai et al. showed that the rate of diffuse stenosis or obstruction of the radial artery was 27.2% in the chronic phase and that significant and frequent obstructive complications resulted from use of a sheath larger than the radial artery. The 3.3Fr catheter system would reduce the risk of obstructive complications at this puncture site.

Aortography with the 3.3Fr catheter provided enough information about the aortic arch and branches of the thoracic aorta (such as the innominate, subclavian, vertebral, and common carotid arteries) for subsequent

CA in all cases. The maximum contrast medium injection rate of 7 mL/s with the 3.3Fr catheter is considered adequate in most cases for performing CA with high quality DSA equipment; however, it can be a limitation for high-flow lesions such as arteriovenous fistulas.

During the 6 months from October 2011 to March 2012, the upgraded 3.3Fr catheter system, which has a hydrophilic coating to achieve better trackability along with a stiff wire and a 40 cm-long sheath for better maneuverability, was used without complication in 318 out of 325 patients scheduled for CA. In seven patients, the operators chose the 4Fr catheter from the beginning instead of the 3.3Fr catheter because records showed that CA with even the 4Fr catheter had been difficult in the past because of tortuous vessels. The 4Fr catheter was used in addition to the 3.3Fr catheter in six patients because of tortuous vessels, although the procedure was completed in only two patients even with use of the larger catheter. On the basis of these findings and the study results, we conclude that the maneuverability of the 3.3Fr catheter and 4Fr catheter is the same.

Kiyosue et al. reported that 108 of 115 patients were able to walk 2 h after the procedure with the 3.3Fr catheter. However, they also reported that five and two patients were only able to walk 2.5 h and 3 h, respectively, after the procedure because the punctures were still oozing 2 or 2.5 h after the procedure. From the viewpoint of risk reduction, we recommended 3 h of bed rest before ambulation. No bleeding complications at the puncture site have been reported in our institute thus far.

Limitation

This study was a retrospective analysis on a limited number of patients. We assessed differences in the duration of the CA procedure and fluoroscopy procedure between the 3.3Fr and 4Fr catheter groups to determine

differences in manipulability. Other major factors or biases may have affected the duration of both procedures. Post-procedure data on variables, such as the time of bed rest or complications at the puncture site were not analyzed because a retrospective survey would not have provided detailed and accurate data on such parameters.

Conclusion

The newly developed 3.3Fr catheter is a feasible alternative to the the 4Fr catheter in performing CA via both the transfemoral and transradial approaches.

All authors declare that they have no conflicts of interest.

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