Evaluation of the usefulness of coronary catheters and 4 Fr insertion sets for transradial access coronarography in comparison with catheters and 5 Fr sets

Piotr Chodór[1], Stanisław Morawski[2], Sylwia Sulik-Gajda[2], Nela Ramus[2], Jacek Kowalczyk[1], Grzegorz Honisz[1], Krzysztof Wilczek[3], Beata Średniawa[1], Zbigniew Kalarus[1]

[1]Department of Cardiology, Congenital Heart Disease and Electrotherapy, Silesian Medical University, Silesian Center for Heart Disease, Zabrze, Poland

[2]Students Scientific Society – Department of Cardiology, Congenital Heart Disease and Electrotherapy, Silesian Medical University, Silesian Center for Heart Disease, Zabrze, Poland

[3]3rd Department of Cardiology, Silesian Medical University, Silesian Center for Heart Disease, Zabrze, Poland

Postep Kardiol Inter 2013; 9, 4 (34): 332–336
DOI: 10.5114/pwki.2013.38860

Abstract

Introduction: Application of transradial arterial access during coronarography, besides pain, means faster patient mobilization and fewer complications. During those procedures, vascular sheaths and 5/6 Fr catheters, and lately 4 Fr catheters, are used.

Aim: To assess the usefulness of 4 Fr catheters and sheaths in comparison to 5 Fr in diagnostic coronarography.

Material and methods: In the period from 5.12.2010 to 27.02.2012, a group of patients who had coronarography with a 4 Fr catheter (n = 20) and a 5 Fr catheter (n = 20) were studied. Technical issues and potential problems related to the use of each catheter were analyzed. Morphology, biochemical parameters, and local complications were analyzed. The assessment included pain intensification during catheter removal and insertion in the VAS/numerical (0–10)/verbal scales and the quality of image obtained during the coronarography.

Results: All the angiograms obtained during all the interventions were of diagnostic value and in invasive cardiologists' opinions, they did not differ statistically in clarity. Moreover, there were no statistically significant differences in radiation/fluoroscopy time, amount of contrast medium, or morphological and biochemical parameters. The size of hematomas in the 4 Fr group was 17.55 ±14.6 cm^2, and in the 5 Fr group 31.07 ±32.11 cm^2, p = 0.12. The average intensity of pain felt during the intervention/at the time of its removal and insertion in the numerical scale was in the 4 Fr group 0.65 ±0.93/0.55 ±0.94 and in the 5 Fr group 1.88 ±1.64/1.42 ±1.61, $p < 0.05$.

Conclusions: Application of 4 Fr catheters allows one to perform a diagnostic procedure with a small number of local and hemorrhagic complications comparable with 5 Fr catheters. Due to reduced pain, it is appropriate to continue studies with the use of 4 Fr catheters and sheaths.

Key words: coronarography, transradial access, 4 French.

Introduction

Coronarographies are performed through 3 alternative arterial accesses, namely, radial, femoral or, nowadays rarely used, brachial artery access (Sones' method).

Application of transradial access, contrary to transfemoral, in persons undergoing coronarography is connected with faster mobilization and shorter hospital stay, as well as fewer local complications, such as hematomas, fistulas, aneurysms, upper limb ischemia or necessity of surgery, while blood transfusion is required more rarely in those patients [1–4]. One of the few drawbacks of this method is pain that the patients suffer from and technical problems related to the procedure. For several decades, constant technological improvement, including device miniaturization, has been observed. Therefore, coronary catheters and insertion sets (vascular sheaths) for hemodynamic diagnosis have smaller diameters, which causes fewer injuries in a patient and as a result reduces pain discomfort.

Decreasing dimensions, apart from benefits for patients, can cause lower quality of the images and techni-

Corresponding author:
Stanisław Morawski MD, Department of Cardiology, Congenital Heart Disease and Electrotherapy, Silesian Medical University, Silesian Center for Heart Disease, Zabrze, Poland, e-mail: morawski.stan@gmail.com
Received: 29.09.2013, **accepted:** 10.10.2013.

cal problems with catheter insertion into coronary artery ostia or keeping it in the ostium while injecting contrast medium. Still in the 1980s and the beginning of the 1990s, the 8 Fr diameter catheters and vascular sheaths were used as a routine procedure. Presently, 5 Fr or 6 Fr catheters and vascular sheaths are applied. Recently, catheters and sheaths of smaller size, i.e. 4 Fr, used by pediatric cardiologists have appeared. There are a few studies comparing the use of 4 Fr and 6 Fr catheters and sheaths applied in diagnostic coronarographies through femoral access [5–7] and one study comparing femoral access and radial access using 4 Fr catheters [8]. Lately, there have been a few reports on 4 Fr catheters applied in stenting procedures through the radial artery [9, 10]. However, they are only single reports and applying transradial access can create additional technical problems, especially in the access through the right radial artery. There are not many reports on experiments using 4 Fr catheters and sheaths using transradial arterial access [8]; therefore a study comparing the use of 4 Fr and 5 Fr catheters and sheaths in diagnostic coronarographies through transradial arterial access was performed.

Aim

The aim of the study is to compare technical aspects of coronarography procedures through transradial access using 4 Fr and 5 Fr catheters and sheaths; to define whether the application of 4 Fr catheters in diagnostic coronarography will not diminish its quality; to compare the complications related to transradial access in patients catheterized with 4 Fr and 5 Fr catheters and sheaths; and to compare pain connected with coronarography performed with 4 Fr and 5 Fr catheters and sheaths.

Material and methods

In the period from 5.12.2010 to 27.02.2012, a group of patients who had coronarography with a 4 Fr catheter (n = 20), the study group, and with a 5 Fr catheter (n = 20), the control group, were analyzed. The decision of catheter and vascular sheath size belonged to the operator. Patients' mean age in the study group was 59.4 ±12.6 years, and in the control group 65.1 ±9.0 (p = 0.16). The number of men was respectively 65% in the study group and 55% in the control group (p = 0.53). The average height and weight in each group were respectively: 1.69 ±0.09 m in the study group vs. 1.69 ±0.07 m in the control group, p = 0.83; and 77.4 ±13.26 kg in the study group vs. 80.85 ±17.27 kg in the control group, p = 0.48. To puncture the right radial artery 21 G × 3.8 cm needles were used, 0.018" × 45 cm guide-wires and 4 Fr × 7 cm and 5 Fr × 7 cm sheaths (Balton, Poland). The sheaths were not covered with a hydrophilic layer. The coronarography was preceded by the modified Allen test using a pulse oximeter [11]. After inserting a vascular sheath, 5000 units of heparin and 5 mg of verapamil were administered through the sheath. Patients beyond the introductory dose did not receive more doses of verapamil. The intervention was performed when the modified Allen test showed the values of 1 or 2; in cases of 3 and 4 the artery was not used for the procedure. The catheters used for coronarography included 5 Fr Judkins catheters (Asahi, Japan) of 3.5 or 4 curvatures and 4 Fr Judkins catheters (Optitorque, Terumo, Japan) of curvatures: left 4 and right 3.5 or 4. Contrast medium was supplied to coronary arteries with an automatic injector. After the intervention the vascular sheath was removed and a Terumo-Band was applied (Teruma-Japan); it was usually removed after 4 h. All the interventions were done by the same operator, with 8-year experience of radial access diagnostic procedures and 22-year experience of femoral access diagnostic interventions.

Analyzing technical aspects of the intervention and potential problems related to each catheter use, the factors taken into consideration included the volume of contrast medium, number of catheters used, frequency of catheter slipping out, doses of spasmolytic and analgesic agents, time of intervention, time of X-ray fluoroscopy and X-ray radiation dose. After the procedure, 2 cardiologists without knowledge of belonging to either of the study groups answered a yes/no question, whether coronarography is of diagnostic value, i.e. whether it is possible to establish a reliable diagnosis and make therapeutic decisions on its basis. They also estimated the clarity of coronarography on a 5-score scale. The evaluation of complications included presence and size of hematoma (cm^2) within 24 h, hemoglobin decrease > 5 g/dl and > 3 g/dl, necessity of blood transfusion, presence of fistula, aneurysm, upper limb ischemia after the intervention, need for surgical intervention on the radial artery, and presence of pulse after the intervention in the radial artery.

Hematoma was defined as an extravasation of blood into the subcutaneous tissue causing lividity and tissue elevation above the level of surrounding skin measured at the point of sheath entry. The measurement of hematomas was done in the largest longitudinal (L) and transverse (W) dimension (a line perpendicular and parallel to the axis of the forearm).

In order to calculate the surface of the hematoma it was assumed that hematoma area corresponds to the shape of an ellipse and it was counted with the formula for the surface area of an ellipse (π*1/2 L*1/2 W).

Subjective pain suffering accompanying vascular sheath insertion and removal was assessed with three scales:

- verbal (0 – no pain, 1 – weak pain, 2 – moderate pain, 3 – strong pain, 4 – very strong pain);
- visual-analogue scale (VAS), patient marks on a 100 mm scale the level of the suffered pain (0 – no pain, 100 – the strongest pain that the patient can imagine);
- numerical scale from 0 to 10 (0 – no pain, 10 – maximal pain that the patient can imagine).

The information in the numerical scale was collected during the procedure and afterwards, and in the verbal and visual-analogue scale up to 24 h after the intervention.

Statistical analysis

Quantitative variables in study groups are presented as arithmetic mean with standard deviation, while qualitative variables are presented as the number of cases with the defined feature together with the percentage that this figure represented in the group. The study groups were compared with each other with Student's *t*-test for independent trials for cases of continuous parameters with normal distribution; otherwise, the non-parametric Mann-Whitney *U* test was applied. Comparative analyses between study groups for qualitative variables were done with the χ^2 test. The value of $p < 0.05$ was assumed to be statistically significant and all the statistical tests were double tests. Statistical analyses were done with the *Statistica* program (version 6.1, StatSoft Inc., Tulsa, OK, USA).

Results

All the angiograms obtained during all the interventions were of diagnostic value and in invasive cardiologists' opinions, they did not differ statistically in clarity; cardiologist 1: 4 Fr group – mean score 4.87 ±0.37, 5 Fr group – mean score 4.95 ±0.16 ($p = 0.39$); cardiologist 2: 4 Fr group – mean score 4.84 ±0.37, 5 Fr group – mean score 5 ±0.0 ($p = 0.07$). The data referring to the technical aspects of the intervention are presented in Table 1.

No differences were observed between groups with respect to radiation exposure, time of fluoroscopy, intervention time, number of contrast injections and its quantity, or the number of catheters used. In 1 patient from the 4 Fr group, a necessity to change catheters from 4 Fr to 5 Fr occurred. The catheter kept falling into the left coronary artery ostium in such a way that the catheter's end was opposite the old dissection in the left coronary artery trunk. Further manipulations were considered too risky and the 4 Fr catheter was changed for a 5 Fr which became located in the left coronary artery trunk in such a way that injecting the contrast medium did not create a threat of left coronary artery trunk dissection. No technical problems were met. Complications are presented in Table 2.

The two groups did not differ in the assessed morphological and biochemical parameters. Presence of a pulse in the artery used in the intervention was found in all the patients in the control examination 24 h after the procedure. None of the patients had vascular complications in the form of considerable bleeding, fistula, aneurysm, upper limb ischemia or other injuries requiring

Table 1. Data concerning technical aspects of the intervention

Variable	4 Fr Group *n* = 20	5 Fr Group *n* = 20	Value of *p*
Applied contrast medium volume [ml]	76.25 ±29.95	80.00 ±21.03	0.65
Number of catheters/patient used during procedure	2.25 ±0.55	2.11 ±0.32	0.32
Frequency of catheter slippage out of coronary artery ostia during contrast administration by an automatic injector	2 (10%)	0 (0%)	0.15
Use of spasmolytic agents: verapamil, dose 5 mg [%]	100	100	NS
Use of spasmolytic agents: verapamil, dose > 5 mg [%]	0	0	NS
Total number of contrast injections into coronary arteries	7.95 ±1.19	7.65 ±0.93	0.38
Number of contrast injections into right coronary artery	2.15 ±0.37	2.3 ±0.57	0.33
Number of contrast injections into left coronary artery	5.8 ±1.15	5.35 ±0.67	0.14
Time of procedure [min]	20.4 ±10.95	16.4 ±5.1	0.15
Time of X-ray fluoroscopy [min]	4.93 ±3.1	3.93 ±1.35	0.19
X-ray radiation dose [mGy]	445.05 ±314.52	465.05 ±290.45	0.84

Table 2. Complications

Variable	4 Fr Group *n* = 20	5 Fr Group *n* = 20	Value of *p*
Hematoma size after 24 h [cm^2]	17.55 ±14.6	31.07 ±32.11	0.12
Hemoglobin decrease > 3 g/dl	0	0	NS
Hemoglobin decrease > 5 g/dl	0	0	NS
Necessity of blood transfusion	0	0	NS
Presence of fistula	0	0	NS
Presence of aneurysm	0	0	NS
Presence of upper limb ischemia	0	0	NS
Necessity of surgical intervention	0	0	NS
Presence of pulse after the intervention on radial artery [%]	100	100	NS

Table 3. Data on suffering pain related to heart catheterization

Variable	4 Fr Group n = 20	5 Fr Group n = 20	Value of p
Numeric scale: 0–10			
Insertion of vascular sheath	0.65 ±0.93	1.88 ±1.64	0.006
Removal of vascular sheath	0.55 ±0.94	1.42 ±1.61	0.045
Verbal scale: 0–4			
Insertion of vascular sheath	0.89 ±0.79	1.33 ±1.07	0.24
Removal of vascular sheath	0.47 ±0.69	1.14 ±1.03	0.028
Visual scale 0–100 (visual-analogue scale – VAS)			
Insertion of vascular sheath	12.53 ±15.56	19.08 ±16.83	0.29
Removal of vascular sheath	7.35 ±9.97	15.35 ±14.54	0.07

surgical intervention. The information on suffering pain during heart catheterization is presented in Table 3.

More severe pain accompanied vascular sheath insertion than its removal, which was confirmed by three scales. A statistically significant difference was observed in feeling pain during insertion and removal of the vascular sheath in the numerical scale (average in 4 Fr group: 0.65 ±0.93/0.55 ±0.94, in 5 Fr group: 1.88 ±1.64/1.42 ±1.61; respectively p = 0.006 and p = 0.045) and in the verbal scale during vascular sheath removal (average in 4 Fr group: 0.47 ±0.70, in 5 Fr group: 1.15 ±1.03; $p < 0.05$).

Discussion

There are only a few reports in the literature concerning the use of 4 Fr sets for heart catheterization in adults and they usually refer to femoral arterial access [5–8].

Technical aspects

The two groups did not differ statistically with respect to intervention time, X-ray fluoroscopy or radiation dose. Moreover, the volume of contrast medium did not differ significantly, though more of it was used in the 5 Fr group, and the number of catheters used was bigger in the 4 Fr group (statistically insignificant). Almost certainly it resulted from the fact of frequent slipping out of the 4 Fr catheter while injecting the contrast medium with the injector, which made the procedure last longer and increased the number of applied catheters. Although the catheter's slipping out at the time of injections can influence the angiography clearness, in the opinion of assessing cardiologists, it was not of any importance. Similar results were observed by Gonzalez *et al*. [12]. While comparing heart catheterization using 4 Fr and 6 Fr catheters through femoral access, the authors obtained results indicating no differences with respect to procedure time, number of catheters used and applied contrast volume. Todd *et al*. [13] in a similar study comparing hemodynamic examination using 4 Fr and 6 Fr catheters through femoral access did not observe any differences in procedure time or X-ray fluoroscopy time; however, they found greater use of contrast medium with the use of 4 Fr catheters. The patients were given verapamil and heparin routinely. No patients required additional verapamil doses due to artery contraction.

In the opinion of the independent researchers, the coronarographies performed with 4 Fr and 5 Fr catheters did not differ with respect to clearness and possibility of making clinical decisions following their results, which means they were diagnostic procedures. Gonzalez *et al*. [12] also observed no differences but their study concerned the comparison of 4 Fr and 6 Fr catheters. However, Todd *et al*. [13], using the score system, found comparable quality of coronarography in contrast injection into the right coronary artery, but lower quality in contrast injections through 4 Fr catheters into the left coronary artery, when they compared the coronarography performed with 4 Fr and 6 Fr catheters.

Complications

Both methods of coronarography in the patients diagnosed according to the plan are safe. No significant differences with respect to hematoma sizes observed 24 h after the intervention were observed; however, they were smaller in the 4 Fr group. Neither group had any local complications or significant decrease of hemoglobin value or necessity of blood transfusion. A similarly lower level or no vascular and hemorrhagic complications were observed by Gonalez *et al*. [12] and Mehta *et al*. [14]. The maintained pulse in radial arteries was found in all the patients after the procedure; however, some reports state that arterial occlusion after transradial procedures amounts to about 5.3–6% [1]. When the 5 Fr guiding catheters were used in percutaneous coronary intervention, the occlusion was 1.1%, and when 6 Fr was used it was 4.8%. There is no information on the use of 4 Fr diagnostic catheters [15].

Feeling pain

Patients undergoing heart catheterization through the radial artery feel pain during injection of local an-

esthesia at the injection site, artery injection, insertion and removal of the vascular sheath, verapamil and heparin administration, and moving guidewires and catheters through the radial and brachial artery. The study assessed the pain during insertion and removal of the vascular sheath. Patients were anesthetized locally using 1 cm 2% lignocaine prior to sheath insertion. None of the patients received morphine. Pain suffering was defined according to a numerical scale during the intervention, so it is the most reliable, whereas verbal and visual scales were used 24 h after the procedure. According to the numerical scale, pain accompanying insertion and removal of 4 Fr sheaths was statistically smaller than with the use of 5 Fr. The results obtained with the verbal and visual scale tend to show smaller pain with the use of 4 Fr sheaths but they are not so unambiguous. The result can be influenced by passing time. Following the observation, it can be stated that the use of 4 Fr catheters for heart catheterization with a similar value of the examination causes less pain related to the examination and minimizes complications. This is another experience on the way to performing diagnostic procedures and percutaneous coronary interventions in out-patient clinics.

Diminishing sizes of sheaths and catheters from 10 Fr to 6 Fr reduced the number of local complications in the use of femoral arterial access, without decreasing the effectiveness of diagnostic examinations and treatment procedures. There are isolated reports indicating that it is possible to perform not only diagnostic procedures using 4 Fr vascular sheaths (inner diameter 4 Fr) and guiding catheters [9, 10]. Another possible method of decreasing local complications with the maintained effectiveness of percutaneous coronary interventions will be to use sheathless guiding catheters with the outer diameter like a 4 Fr sheath.

Study limitations include the small number of patients in the study, the study conducted in one research centre, and procedures executed by one operator.

Conclusions

No differences with respect to the analyzed technical aspects of the procedure performed from the radial arterial access were observed in relation to the 4 Fr or 5 Fr size of the applied catheters and vascular sheaths. Application of 4 Fr catheters and sheaths allows one to diagnose coronary arteries. Coronarographies using 4 Fr catheters and sheaths show a low, comparable with 5 Fr catheters and sheaths, number of local and hemorrhagic complications. Pain in both groups was at a low level, lower with the use of catheters and 4 Fr sheaths. The authors believe that it is appropriate to continue studies on the use of catheters and 4 Fr sheaths.

References

1. Agostini P, Biondi-Zoccai GG, de Benedictis ML, et al. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures; systematic overview and meta-analysis of randomized trials. J Am Coll Cardiol 2004; 44: 349–356.
2. Jolly SS, Amlani S, Hamon M, et al. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. Am Heart J 2009; 157: 132–140.
3. Kiemeneij F, Laarman GJ, Odekerken D, et al. A randomized comparison of percutaneous transluminal coronary angioplasty by the radial, brachial and femoral approaches: the Access study. J Am Coll Cardiol 1997; 29: 1269–1275.
4. Jang JS, Jin HY, Seo JS, et al. The transradial versus the transfemoral approach for primary percutaneous coronary intervention in patients with acute myocardial infarction: a systematic review and meta-analysis. EuroIntervention 2012; 8: 501–510.
5. Laurenço C, António N, Santos L, et al. Results of routine use of 4 Fr catheters for diagnostics catheterization in a cath lab. Rev Port Cardiol 2009; 28: 1377–1392.
6. Durst R, Lotan C, Nassar H, et al. Comparison of 4 and 6 French catheters for coronary angiography: real-world modeling. Isr Med Assoc J 2007; 9: 290–293.
7. Danzi GB, Capuano C, Sesana M, et al. A randomised comparison of the use of 4 and 6 French diagnostics catheters: the limits of downsizing. Int J Cardiol 2001; 79: 113–117.
8. Hudelo C, Maillard L, Quilliet L, et al. Comparison of coronary angiography by the left radial and right femoral approach with 4 French catheters. Archives des Maladies du Coeur et des Vaisseaux 2000; 93: 813–819.
9. Meier B, Binder RK, Vogel R. Coronary stenting through 4 French diagnostic catheter. Catheter Cardiovasc Interv 2012; 79: 122–114.
10. Takeshita S, Tanaka S, Saito S. Coronary intervention with 4-French catheters. Catheter Cardiovasc Interv 2010; 75: 735–739.
11. Barbeau GR, Arsenault F, Dugas L, et al. Evaluation of the ulnopalmar arterial arches with pulse oximetry and plethysmography: comparison with the Allen's test in 1010 patients. Am Heart J 2004; 147: 489–493.
12. Gonzalez MA, Ben-Dor I, Gaglia MA, et al. Quantitative comparison of coronary angiograms between 4 French catheters with an advanced cardiovascular injection system and 6 French catheters with manual injection. Catheter Cardiovasc Interv 1012; 79: 843–848.
13. Todd DM, Hubner PJ, Hudson N, et al. Multicentre, prospective, randomized trial of 4 vs. 6 French catheters in 410 patients undergoing coronary angiography. Catheter Cardiovasc Interv 2001; 54: 269–275.
14. Mehta H, Chatterjee T, Windecker S, et al. Four French catheters for diagnostic coronary angiography. Catheter Cardiovasc Interv 2003; 58: 275–280.
15. Dahm JB, Vogelgesang D, Hummel A, et al. A randomized trial of 5 vs. 6 French transradial percutaneous coronary interventions. Catheter Cardiovasc Interv 2002; 57: 172–176.