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Comparison of 4-French versus 5-French sheaths for diagnostic coronary angiography via the snuffbox approach

Running title: Short hemostasis duration of the snuffbox approach

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Abstract

Background: Although a shorter hemostasis duration would be expected when compared with the conventional radial approach as the diameter of the distal radial artery is smaller than that of the conventional radial artery, the optimal duration of hemostasis in diagnostic coronary angiography (CAG) via the distal radial approach, termed the snuffbox approach, has not been well investigated.

Methods: Data from 171 patients were retrospectively collected (55 and 116 patients in the 4-French [Fr] and 5-Fr sheath groups, respectively). The patients had suspected myocardial ischemia and were undergoing diagnostic CAG via the snuffbox approach at a single center between January 2019 and August 2019.

Results: The mean age of the study population was 67.6 ± 11.0 years, and 69% were male. The left snuffbox approach was performed in 146 (85.4%) patients. The mean snuffbox puncture time, defined as the time interval between local anesthesia and sheath cannulation, was 145.1 ± 120.8 s. The hemostasis duration was significantly shorter in the 4-Fr sheath

group than in the 5-Fr sheath group (70 [62–90] vs. 120 [120–130] min; $p < 0.001$). There were local hematomas, defined as ≤ 5 cm in diameter, at the puncture site in 8 (4.7%) patients. Moreover, there were no conventional and distal radial artery occlusions, assessed by manual pulse, after hemostasis in the study population during hospitalization.
Conclusions: Successful hemostasis was obtained within 2 h for diagnostic CAG via the snuffbox approach using the 4-Fr or 5-Fr sheaths.
Key words: coronary angiography, coronary catheterization, hemostasis, radial artery

Introduction

The conventional radial artery approach in coronary angiography (CAG) is currently preferred due to several advantages (e.g., reduced vascular complications, patient comfort, and early ambulation) when compared with the femoral approach [1–3]. Because of these advantages, it is recommended as the first and standard approach for CAG and percutaneous coronary intervention (PCI) in the current guidelines [4]. However, radial artery occlusion remains the most common local vascular complication, with a reported incidence of between 0.8% and 30% [5]. Furthermore, significant access-site complications, including pseudoaneurysm and arteriovenous fistulas, which occasionally require surgery or transfusions, cannot be avoided [6].

Recently, the distal radial approach, termed the snuffbox approach, has gained the interest of interventional cardiologists because it may have fewer complications than the conventional radial artery approach. The feasibility of the snuffbox approach for coronary catheterization has been demonstrated in several studies, showing potential benefits in terms of less bleeding and few access-site complications [7–14]. With respect to hemostasis in the snuffbox approach, a shorter hemostasis duration would be expected compared with the conventional radial approach as the diameter of the distal radial artery is significantly smaller than that of the conventional radial artery [15, 16]. However, the optimal duration for hemostasis after CAG via the snuffbox approach has not been well investigated. Therefore, the aim of the study was to investigate the hemostasis duration after diagnostic CAG via the snuffbox approach using either a 4-French (Fr) or 5-Fr sheath.

Methods

Data was collected retrospectively from patients with suspected myocardial ischemia, at a single center, who underwent diagnostic CAG via the snuffbox approach between January 2019 and August 2019. A single operator (Y.K.) attempted the snuffbox approach in patients who had a well-palpable pulse in the anatomical snuffbox area. The study protocol was approved by the institutional review board of Chonnam National University Hospital (approval number: CNUH-2019-280), who waived the requirement for informed consent owing to the retrospective observational study design.

Local anesthesia was achieved through a 1-mL lidocaine hydrochloride injection into an anatomical snuffbox with a 26-gauge needle. Thereafter, puncture was performed using a 21-gauge open needle using the anterior wall puncture technique. After a successful puncture, a 0.018-inch hair wire was inserted; this was followed by the insertion of a 4-Fr or 5-Fr radial sheath (Prelude Radial®; Merit Medical, UT, USA). The selection of the sheath size was left at the physician's discretion. After successful sheath cannulation, a cocktail including 2.5 mg of verapamil, 0.2 mg of nitroglycerine, and 3000 units of unfractionated heparin was administered before catheterization in all patients. Hemostasis was obtained using a compressive bandage with gauze (**Suppl. Video 1**). A local hematoma was defined if the hematoma was ≤ 5 cm in diameter according to Early Discharge After Transradial Stenting of Coronary Arteries (EASY) classification I [17].

Statistical analysis

All categorical variables were presented as numbers with percentages and were analyzed using the χ^2 test or Fisher exact test. Continuous variables were expressed as mean with standard deviation or median with interquartile ranges and were compared using the un-paired t-test or Mann-Whitney U test, as appropriate. Statistical analyses were conducted using R version 3.5.0 (R Foundation for Statistical Computing, Vienna, Austria) and SPSS 22.0 for Windows (SPSS-PC, Chicago, IL, USA).

Results

Between January 2019 and August 2019, there were a total of 474 consecutive patients who had planned to undergo CAG or PCI by single operator. Among them, cases of conventional radial or femoral approach, failed snuffbox punctures, failed CAG, PCI, and

CAG using a 6-Fr sheath were excluded. Therefore, a total of 171 patients were selected who underwent successful diagnostic CAG via the snuffbox approach using a 4-Fr (n = 55) or 5-Fr sheath (n = 116) (Fig. 1).

During the study period, the success rate with the snuffbox approach was 97.2% (380/391). Baseline clinical characteristics of the study population, including the 4-Fr and 5-Fr sheath groups, are shown in Table 1. The mean age was 67.6 ± 11.0 years and 118 (69.0%) patients were male. There were no differences in body mass index, systolic and diastolic blood pressure, hypertension, diabetes mellitus, chronic kidney disease, and periprocedural anti-thrombotic medication. The 5-Fr sheath group had a higher composition of men than the 4-Fr sheath group. The most common reason for CAG was a suspicious coronary artery disease (95.3%).

The mean and median hemostasis durations were significantly shorter in the 4-Fr sheath group than the 5-Fr sheath group, as shown in Figure 2 (88.4 ± 42.0 and 70 [62–90] min vs. 134.0 ± 35.2 and 120 [120–130] min; $p < 0.001$). With respect to puncture-site complications, there were no conventional and distal radial artery occlusions, assessed by manual pulse, during hospitalization. Local hematomas occurred in 8 (4.7%) cases, including 3 cases in the 4-Fr group and 5 cases in the 5-Fr group. There were no cases of puncture-related local numbness or major bleeding complications requiring surgery or transfusions, as shown in Table 2.

Discussion

In the present study, the median hemostasis durations were about 1 h and 2 h in the 4-Fr and 5-Fr sheath groups, respectively. Moreover, there were no conventional and distal radial artery occlusions in any of the patients during hospitalization. According to available research, this is the first study reporting hemostasis duration during the snuffbox approach according to sheath size.

Although several studies have reported that 3 h could be enough to achieve successful hemostasis with the compressive bandage method or using a radial compression device, they did not suggest an optimal hemostasis duration according to sheath size, in PCI or in CAG [7–9]. Conversely, the current study revealed common hemostasis duration used in patients who underwent diagnostic CAG using a 4-Fr or 5-Fr sheath. Despite the relatively short hemostasis durations (1 h with 4-Fr and 2 h with 5-Fr sheaths), successful hemostasis,

without access-site complications, was achieved in most patients; local hematoma (EASY classification I) occurred in only 4.7% of the study population. Therefore, diagnostic CAG via the snuffbox approach, using a small size sheath, would be beneficial for patients who require an earlier discharge to return to their daily activities.

There were no conventional radial artery occlusions observed in the present study. Although there is concern that the sheath inserted through the snuffbox approach could damage the conventional radial artery, several studies demonstrated that no conventional radial artery occlusion was observed with successful hemostasis [7–10]. Hemostatic compression after conventional radial approach can lead to blood flow interruption in the conventional radial artery; the absence of blood flow during hemostasis was a potent predictor of conventional radial artery occlusion [18, 19]. Thus, the snuffbox approach could be useful to preserve an access route in patients who may have a repeat coronary catheterization. In addition, the present study suggests that the snuffbox approach may be appropriate in providing an alternative access route in patients with chronic kidney disease who need to preserve their radial artery for the creation of an arteriovenous fistula in the future. However, a further prospective study is needed to confirm the patency of the conventional radial artery after the snuffbox approach using functional and imaging assessment.

Limitations of the study

This study has several limitations. First, this study has the inherent limitations associated with retrospective studies with small sample sizes. Second, the hemostasis duration after the snuffbox approach was evaluated without a control group. Therefore, the presented results should only be regarded as hypothesis generating. Third, although a reduction in the risk of conventional and distal radial artery occlusion is a potential benefit of the snuffbox approach, the occurrence of radial artery occlusion was evaluated only by manual pulse, without vascular ultrasonography. Furthermore, the patency of both radial arteries was not evaluated after discharge. These limitations could lead to an underestimation of access-site complications such as pseudoaneurysm or delayed radial artery occlusion.

Conclusions

Successful hemostasis was obtained within 2 h for diagnostic CAG via the snuffbox

approach using the 4-Fr or 5-Fr sheaths. Further, large randomized control trials are needed to confirm the ideal hemostasis duration and the safety of the snuffbox approach in CAG and even PCI.

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Conflict of interest: None declared

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Table 1. Baseline clinical characteristics of the study population.

Patients	Total (n = 171)	4 Fr (n = 55)	5 Fr (n = 116)	P
Demographics				
Age [years]	67.6 ± 11.0	68.0 ± 10.3	67.4 ± 11.3	0.752
Male	118 (69.0%)	24 (43.6%)	94 (81.0%)	< 0.001
Body mass index [kg/m^2]	24.9 ± 3.5	24.5 ± 4.1	25.2 ± 3.2	0.345
Vital signs				
SBP [mmHg]	127.8 ± 21.4	129.6 ± 21.2	127.0 ± 21.6	0.462
DBP [mmHg]	76.2 ± 14.2	77.9 ± 12.9	75.4 ± 14.8	0.274
Heart rate [bpm]	76.4 ± 13.5	79.3 ± 13.1	75.0 ± 13.5	0.055
Risk factors				
Hypertension	130 (76.0%)	37 (67.3%)	93 (80.2%)	0.098
Diabetes mellitus	52 (30.4%)	14 (25.5%)	38 (32.8%)	0.428
Dyslipidemia	102 (59.6%)	29 (52.7%)	73 (62.9%)	0.270
Current smoking	27 (15.8%)	6 (10.9%)	21 (18.1%)	0.327
CKD (eGFR < 60 mL/min/1.73 m^2)	42 (24.6%)	12 (21.8%)	30 (25.9%)	0.701
Laboratory findings				
Hemoglobin [g/dL]	13.0 ± 2.0	12.7 ± 1.9	13.1 ± 2.1	0.231
Platelets [10^3/mm^3]	222 ± 67	231± 76	217 ± 63	0.230
PT-INR	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.1	0.785
Final ACT	244.4 ± 65.2	250.8 ± 67.2	241.4 ± 64.2	0.378
Reasons for CAG				
Investigation for CAD	163 (95.3%)	52 (94.5%)	111 (95.7%)	0.741
Valvular heart disease	8 (4.7%)	3 (5.5%)	5 (4.3%)	0.741
Periprocedural anti-thrombotic medication				
ASA loading	69 (40.4%)	22 (40.0%)	47 (40.4%)	0.949
Clopidogrel loading	90 (52.6%)	34 (61.8%)	56 (48.3%)	0.105
ASA	162 (94.7%)	49 (89.1%)	113 (97.4%)	0.056
P2Y12 inhibitor	159 (93.0%)	49 (89.1%)	110 (94.8%)	0.293
Clopidogrel	153 (89.5%)	48 (87.3%)	105 (90.5%)	
Ticagrelor	6 (3.5%)	1 (1.8%)	5 (4.3%)	
Oral anticoagulation	14 (8.2%)	4 (7.3%)	10 (8.6%)	0.799
UFH or LMWH injection	171 (100%)	55 (100%)	116 (100%)	

Values are presented as mean ± standard deviation or as number (%). ACT — activated clotting time; ASA — acetylsalicylic acid; CAD — coronary artery disease; CAG — coronary angiography; CKD — chronic kidney disease; DBP — diastolic blood pressure; eGFR — estimated glomerular filtration rate; LMWH — low molecular weight heparin; PT-INR — prothrombin time-international normalized ratio; SBP — systolic blood pressure; UFH — unfractionated heparin

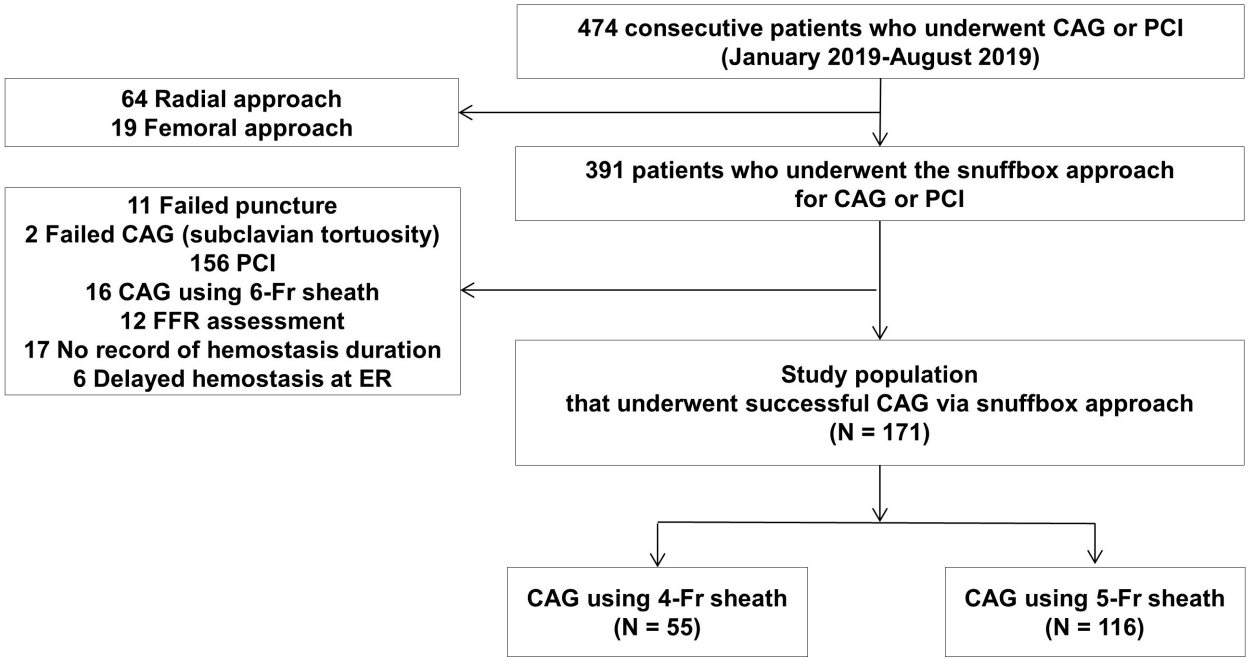
Table 2. Snuffbox characteristics and puncture site complications.

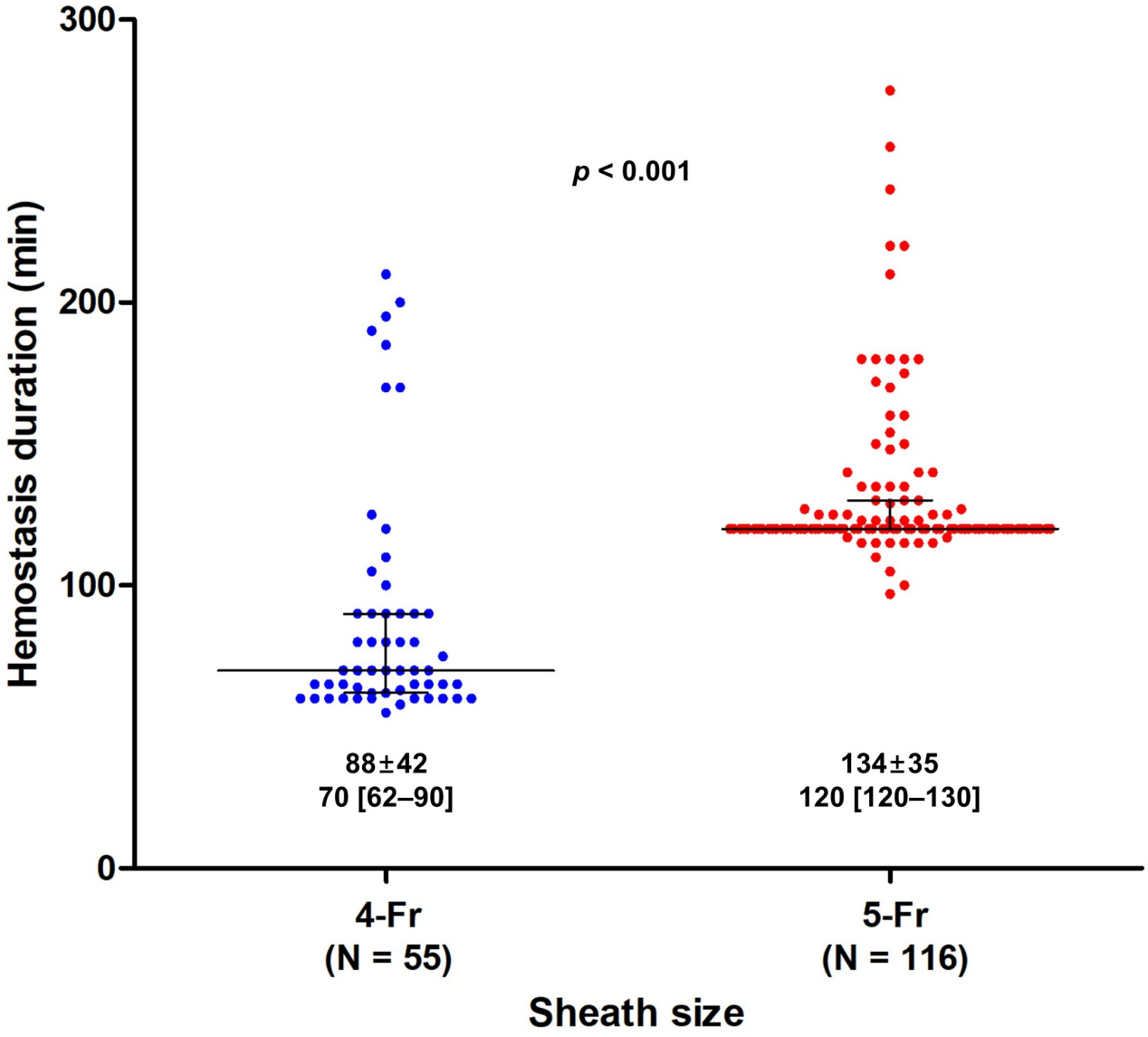
Patients	Total (n = 171)	4 Fr (n = 55)	5 Fr (n = 116)	P
Snuffbox approach details				
Puncture time				
Mean [s]	145.1 ± 120.8	161.2 ± 148.3	137.4 ± 105.1	0.288
Median [s]	104 [77.5–163]	105 [84.5–176]	104 [72–152]	0.371
Left snuffbox approach	146 (85.4%)	51 (92.7%)	95 (81.9%)	0.101
Hemostasis duration				
Mean [min]	118.4 ± 40.0	88.4 ± 42.0	134.0 ± 35.2	< 0.001
Median [min]	120 [93.5–125]	70 [62–90]	120 [120–130]	< 0.001
Puncture site complications				
Conventional RA occlusion	0 (0%)	0 (0%)	0 (0%)	
Distal RA occlusion	0 (0%)	0 (0%)	0 (0%)	
Local numbness	0 (0%)	0 (0%)	0 (0%)	
Local hematoma	8 (4.7%)	3 (5.5%)	5 (4.3%)	0.934

Values are presented as mean ± standard deviation or as number (%). RA — radial artery

Figure 1. Study flow chart; CAG — coronary angiography; PCI — percutaneous coronary intervention; FFR — fractional flow reserve; ER — emergency room.

Figure 2. Hemostasis duration during the snuffbox approach according to sheath size.


474 consecutive patients who underwent CAG or PCI
(January 2019-August 2019)
64 Radial approach
19 Femoral approach
391 patients who underwent the snuffbox approach
for CAG or PCI
11 Failed puncture
2 Failed CAG (subclavian tortuosity)
156 PCI
16 CAG using 6-Fr sheath
12 FFR assessment
17 No record of hemostasis duration
6 Delayed hemostasis at ER
Study population
that underwent successful CAG via snuffbox approach
(N = 171)
CAG using 4-Fr sheath
(N = 55)
CAG using 5-Fr sheath
(N = 116)


300
200
100
0
Hemostasis duration (min)
p < 0.001
88±42
70 [62–90]
134±35
120 [120–130]
4-Fr
(N = 55)
5-Fr
(N = 116)
Sheath size