



Safety and efficacy of transradial coronary angiography and intervention in patients older than 80 years: from the Korean Transradial Intervention Prospective Registry

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Abstract

Background Radial artery access for coronary procedures is a safe and beneficial technique. However, elderly patients have been considered as a higher risk group of access site related complications compared to younger patients. This study was conducted to investigate the feasibility and safety of transradial coronary angiography or intervention in the elderly. **Methods** A total of 6132 patients from Korean Transradial Intervention Prospective Registry at 20 centers were analyzed. Patients were divided into the non-elderly group ($n = 5667$) and the elderly (≥ 80 years) group ($n = 465$). Using propensity score matching, the elderly group ($n = 465$) was compared with one-to-one matched the non-elderly group ($n = 465$). **Results** After propensity score matching, mean age was 64.3 ± 10.3 years in the non-elderly group and 83.5 ± 3.3 years in the elderly group. There was no difference of procedural characteristics, procedural and fluoroscopic times. Access site cross-over rate was not different between the non-elderly group and elderly group (7.5% vs. 6.2%, $P = 0.074$). Bleeding complications occurred similarly in two groups (2.6% of the non-elderly group vs. 1.9% of the elderly group, $P = 0.660$). Access site complications were 1.9% of the non-elderly group and 0.9% of the elderly group ($P = 0.263$). Both of in hospital death and cardiovascular death for one year were also similar between two groups. **Conclusions** Transradial angiography or intervention was safe and feasible in elderly patients. Complication rates and clinical outcomes in elderly patients were comparable with those in non-elderly patients.

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Keywords: The elderly patients; Transradial coronary angiography; Transradial coronary intervention

1 Introduction

Advanced age population is gradually increasing in

world wide. Coronary artery disease is an important cause of death in elderly patients.^[1] For elderly patients, there have been trends to treat more conservatively due to multiple comorbidities, lower physical performance, and high rate of complications from invasive procedure.^[2] Transradial access (TRA) for coronary angiography or intervention has decreased access related complications, such as bleeding, compared to transfemoral access.^[3] However, there is limited evidence comparing the safety or feasibility of TRA in elderly patients with younger patients. Therefore, we compared the procedural and clinical outcomes of TRA in elderly patients (≥ 80 years old) to those in younger patients.

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2 Methods

2.1 Study population

The study patients were selected from The Korean Transradial Intervention (KOTRI) a prospective, observational multicenter registry conducted at 20 hospitals in Korea.^[4] Study patients at each institute were enrolled for six months in KOTRI registry, but an entire study population was enrolled between May 2012 and January 2015 due to different time process for the Institutional Review Board (IRB) approval. The registry firstly included 6793 patients, but more consecutive patients were enrolled in several centers later. A total of 7300 patients were enrolled for the latest version. Clinical, laboratory, procedural and outcome data were collected. All subjects were clinically followed for one month and patients who underwent percutaneous coronary intervention (PCI) were followed for one year after procedure by visiting or telephone interview. The IRB of each center approved this study, and written informed consent was obtained from each patient. Exclusion criteria were patients with < 18 years old, other vascular access rather than radial artery and inappropriate data.

2.2 Cardiac catheterization

Each cardiac catheterization was performed by physician's discretion and strategy by each institution. TRA coronary procedures were performed 139 operators. For TRA coronary angiography, 92 operators were more experienced (≥ 500 cases) and 10 operators were newer (< 50 cases). For TRA intervention, 72 operators had more experience, although 16 operators had less experience.

2.3 Definitions and outcomes

The elderly group was defined as ≥ 80 years old. We compared procedural and clinical outcomes between the elderly group and the non-elderly group. Procedural outcomes for this study included used sheath and catheter size, number of catheters, access site crossover and procedural time. Access site crossover was defined as a change of access site between the start of procedure and the end of procedure. All deaths were considered as cardiac cause deaths unless a definite non-cardiac cause was established. Safety outcome was defined as bleeding and access site related complications. Bleeding was defined according to a consensus report from Bleeding Academic Research Consortium.^[5] Puncture time was defined as the duration between local anesthesia and the end of sheath insertion. Angiography time was the duration between the insertion of sheath and the end of coronary angiography. PCI time was defined as the duration from the insertion of guiding catheter to the end of PCI.

2.4 Statistical analysis

Continuous variables were expressed as mean $\pm$ SD. To compare continuous variables, the Student *t*-test or Wilcoxon rank-sum test was conducted. We conducted the Chi-square test or Fisher's exact test for comparing categorical variables. To compare continuous variables the Student *t*-test was conducted.

To adjust for differences between the elderly group and the non-elderly group, we conducted propensity score one to one matched analysis. Logistic regression model was used to estimate a propensity score. The following variables were used for the propensity score model: sex, hypertension, diabetes mellitus, chronic kidney disease, prior myocardial infarction, smoking history, prior cerebrovascular event, prior PCI, and clinical indication for CAG and PCI. Propensity score match was conducted using R extension pack (R version 2.8) with SPSS software (SPSS Inc., 18.0, Chicago, IL, USA). After propensity score matching, we checked the balance in baseline covariates between the elderly group and younger group using McNemar's test and a paired *t*-test or the Wilcoxon signed rank test. Statistical analysis was performed using the SPSS 18. A *P* value < 0.05 was considered statistically significant.

3 Results

Among a total of 7300 registered patients, 1168 patients were excluded (Figure 1). A total of 6132 patients with firstly TRA approach was analyzed. Baseline clinical characteristics are shown in Table 1. Compared with younger patients, elderly patients had a higher prevalence of female gender, hypertension, chronic kidney disease, prior PCI, prior cerebrovascular accident and acute coronary syndrome, but a lower prevalence of current smoker. After propensity score matching, clinical characteristics were not different between two groups. Among other clinical diagnosis, heart failure was more common in the elderly group (21.4% vs. 9.1%), but vasospastic angina was more common in the non-elderly group (26.5% vs. 6.1%).

Procedural characteristics are listed in Table 2. Among patients with firstly TRA tried, access site cross-over to other vascular access, such as femoral, ulnar or brachial artery, or contralateral radial access for coronary angiography occurred in 6.2%, 29 of 465 elderly patients and 5.1%, 288 of 5667 non-elderly patients ($P = 0.326$). Although access site crossovers due to tortuous vessel and subclavian artery occlusion were more common in the elderly group, the significance of difference was disappeared after propensity

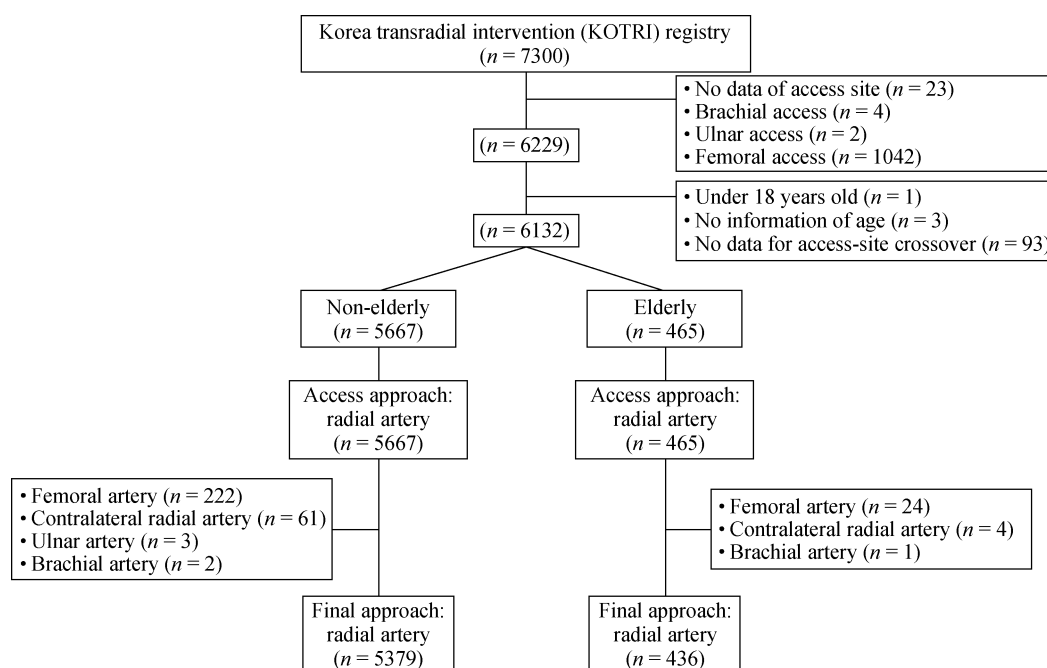


Figure 1. The selection of the patients.

Table 1. Baseline clinical characteristics of study population.

	Overall population			Propensity-matched population		
	Non-elderly (n = 5667)	Elderly (n = 465)	P-value	Non-elderly (n = 465)	Elderly (n = 465)	P-value
Age, yrs	62.2 ± 10.5	83.5 ± 3.3	< 0.001	64.3 ± 10.3	83.5 ± 3.3	< 0.001
Male	3543 (62.5%)	183 (39.4%)	< 0.001	183 (39.4%)	183 (39.4%)	0.999
Medical history						
Hypertension	3172 (56.0%)	344 (74.0%)	< 0.001	343 (77.8%)	343 (74.0%)	0.999
Diabetes mellitus	1506 (26.6%)	121 (26.0%)	0.827	121 (26.0%)	121 (26.0%)	0.999
Dyslipidemia	1107 (19.5%)	85 (18.3%)	0.542	87 (18.7%)	85 (18.3%)	0.933
Chronic kidney disease	66 (1.2%)	11 (2.4%)	0.032	12 (2.6%)	11 (2.4%)	0.999
Current smoker	1280 (22.6%)	54 (11.6%)	< 0.001	50 (10.8%)	54 (11.6%)	0.755
Prior MI	437 (7.7%)	39 (8.4%)	0.652	34 (7.3%)	39 (8.4%)	0.626
Prior PCI	1211 (21.4%)	122 (26.2%)	0.016	119 (25.6%)	122 (26.2%)	0.881
Prior CVA	306 (5.4%)	34 (7.3%)	0.091	30 (6.5%)	34 (7.3%)	0.698
Clinical diagnosis			< 0.001			0.984
STEMI	191 (3.4%)	22 (4.7%)		25 (5.4%)	22 (4.7%)	
NSTEMI	381 (6.7%)	56 (12.0%)		53 (11.4%)	56 (12.0%)	
Unstable angina	1482 (26.1%)	130 (28.0%)		126 (27.1%)	130 (28.0%)	
Stable angina	2168 (38.3%)	126 (27.1%)		129 (27.7%)	126 (27.1%)	
Others	1445 (25.5%)	131 (28.2%)		132 (28.4%)	131 (28.2%)	

Data were presented as mean ± SD or n (%). CVA: cerebrovascular accident; MI: myocardial infarction; NSTEMI: non ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction.

score matching analysis. All of the procedures were successfully performed.

Compared with the non-elderly patients, more frequently the left radial artery and higher number of catheters were used in the elderly patients. Also, PCIs were performed more in the elderly group compared to in the non-elderly

group. Puncture time, CAG time, PCI time or total amounts of contrast used were not different between two groups. After propensity score matching analysis, procedural characteristics of the two groups were not different.

After propensity score matching analysis, any type of bleeding occurred in 9 patients (1.9 %) of the elderly group

Table 2. Procedural characteristics of coronary angiography.

	Overall population			Propensity-matched population		
	Non-elderly (n = 5667)	Elderly (n = 465)	P-value	Non-elderly (n = 465)	Elderly (n = 465)	P-value
Access site cross-over	288 (5.1%)	29 (6.2%)	0.326	35 (7.5%)	29 (6.2%)	0.517
Puncture failure	97 (1.7%)	8 (1.7%)	0.999	14 (3.0%)	8 (1.7%)	0.280
Vessel tortuosity	44 (0.8%)	9 (1.9%)	0.017	5 (1.1%)	9 (1.9%)	0.420
Need for larger catheter	33 (0.6%)	3 (0.6%)	0.999	5 (1.1%)	3 (0.6%)	0.725
Routine practice for PCI	32 (0.6%)	3 (0.6%)	0.999	4 (0.9%)	3 (0.6%)	0.999
Vasospasm or small radial artery	19 (0.3%)	2 (0.4%)	0.999	3 (0.6%)	2 (0.4%)	0.999
Assess site complication	11 (0.2%)	1 (0.1%)	0.999	1 (0.2%)	1 (0.2%)	0.999
Contraindication for radial access	4 (0.1%)	0 (0.0%)	0.999	0 (0.0%)	0 (0.0%)	0.999
Failure of catheter engagement	4 (0.1%)	0 (0.0%)	0.999	0 (0.0%)	0 (0.0%)	0.999
Subclavian artery occlusion	3 (0.1%)	2 (0.4%)	0.049	1 (0.2%)	2 (0.4%)	0.999
Unstable vital status	6 (0.1%)	0 (0.0%)	0.999	0 (0.0%)	0 (0.0%)	0.999
Others	11 (0.2%)	0 (0.0%)	0.621	1 (0.2%)	0 (0.0%)	0.999
Unknown	24 (0.4%)	1 (0.2%)	0.718	1 (0.2%)	1 (0.2%)	0.999
1 st Approach site			0.009			0.394
Left radial	1509 (26.6%)	150 (32.3%)		137 (29.5%)	150 (32.3%)	
Right radial	4158 (73.4%)	315 (67.7%)		328 (70.5%)	315 (67.7%)	
Sheath size			0.099			0.139
4F	1209 (21.4%)	76 (16.3%)		97 (20.9%)	76 (16.3%)	
5F	2046 (36.1%)	193 (41.5%)		162 (34.8%)	193 (41.5%)	
6F	2381 (42.0%)	192 (41.3%)		201 (43.2%)	192 (41.3%)	
7F	30 (0.5%)	4 (0.9%)		5 (1.1%)	4 (0.9%)	
Sheathless	1 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Number of diagnostic catheter						
Left coronary artery			0.016			0.052
1	5543 (97.8%)	456 (98.1%)		450 (96.8%)	456 (98.1%)	
2	113 (2.0%)	5 (1.1%)		1.4 (3.0%)	5 (1.1%)	
> 3	11 (0.2%)	4 (0.9%)		1 (0.2%)	4 (0.9%)	
Right coronary artery			0.033			0.533
1	5580 (98.5%)	451 (97.0%)		456 (98.1%)	451 (97.0%)	
2	80 (1.4%)	12 (2.6%)		8 (1.7%)	12 (2.6%)	
> 3	7 (0.1%)	2 (0.4%)		1 (0.2%)	2 (0.4%)	
Underwent PCI	1675 (29.6%)	173 (37.8%)	< 0.001	149 (32.0%)	176 (37.8%)	0.074
Puncture time, min	2.5 ± 2.9	2.4 ± 2.8	0.536	2.6 ± 3.5	2.4 ± 2.8	0.234
CAG time, min	11.0 ± 9.0	11.5 ± 8.8	0.265	11.1 ± 8.8	11.5 ± 8.8	0.579
PCI time, min	31.8 ± 20.9	29.2 ± 23.6	0.121	29.8 ± 18.8	29.2 ± 23.6	0.794

Data were presented as n (%) or mean ± SD. CAG: coronary angiography; F: French; PCI: percutaneous coronary intervention.

and 12 patients (2.6 %) of the non-elderly group ($P = 0.660$) (Table 3). Access site related complications similarly occurred in both groups (0.9% vs. 1.9%, $P = 0.263$).

Among patients with clinical follow up during 1 year, all cause deaths were more common in the elderly group than in the non-elderly group (5.7% vs. 0.9%, $P < 0.001$), even after propensity score matching analysis (5.7% vs. 1.3%, $P = 0.002$). However, cardiovascular deaths were not significantly different between two groups (2.1% vs. 0.6%, $P = 0.177$) after propensity score matching analysis.

4 Discussion

This prospective cohort study showed that access site crossover rate, procedural characteristics, bleeding and vascular complications were not different between elderly patients and non-elderly patients.

TRA has significant advantages compared to transfemoral access in elderly patients. Elderly patients have higher incidence of comorbidities which increases the possibility for complications.^[2] TRA reduced access site related complica-

Table 3. Bleeding and access site related complications.

	Overall population			Propensity-matched population		
	Non-elderly (n = 5667)	Elderly (n = 465)	P-value	Non-elderly (n = 465)	Elderly (n = 465)	P-value
Any bleeding	70 (1.2%)	9 (1.9%)	0.197	12 (2.6%)	9 (1.9%)	0.660
Type of bleeding						
Type 1	44 (0.8%)	2 (0.4%)	0.579	7 (1.5%)	2 (0.4%)	0.178
Type 2	16 (0.3%)	2 (0.4%)	0.651	3 (0.6%)	2 (0.4%)	0.999
Type 3a	7 (0.1%)	3 (0.6%)	0.035	2 (0.4%)	3 (0.6%)	0.999
Type 3b	1 (0.0%)	1 (0.2%)	0.146	0 (0.0)	1 (0.2%)	0.999
Type 4	2 (0.0%)	0 (0.0)	0.999	1 (0.2%)	0 (0.0)	0.999
Type 5a	0 (0.0)	1 (0.2%)	0.076	0 (0.0)	1 (0.2%)	0.999
Access site complication	51 (0.9%)	4 (0.9%)	0.999	9 (1.9%)	4 (0.9%)	0.263
Major hematoma	1 (0.0%)	0 (0.0)	0.999	0 (0.0)	0 (0.0)	0.999
Minor hematoma	40 (0.7%)	3 (0.6%)	0.999	7 (1.5%)	3 (0.6%)	0.341
Dissection	8 (0.1%)	1 (0.2%)	0.999	1 (0.2%)	1 (0.2%)	0.999
Fistula	1 (0.0)	0 (0.0)	0.999	0 (0.0)	0 (0.0)	0.999
Perforation	1 (0.0)	0 (0.0)	0.999	1 (0.2%)	0 (0.0)	0.999

Data were presented as n (%).

tions such as puncture site bleeding, pseudoaneurysm and retroperitoneal hemorrhage, than transfemoral procedure in elderly patients.^[6-8] Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndrome (RIVAL) study in elderly (≥ 75 years old) patients showed that TRA was associated with significantly lower rates of major bleeding compared to transfemoral access.^[9] However, there was a trend of increased rate of bleeding complication of TRA in advanced age in RIVAL trial. Bleeding complications in octogenarians occurred in 5.3% of patients with TRA in RIVAL trial.^[9] However, all types of bleeding complications occurred only in 2.0% of elderly patients. Compared with in RIVAL trial, less performed PCI (63.4% vs. 37.1%) and smaller sized sheath (14.7% vs. 58.2% of less than five French arterial sheaths) in the current study might have resulted in less bleeding complication.

Elderly patients are more like to have challenging vascular anatomy. In clinical considerations, anatomical tortuosity in brachial or subclavian artery can result in more difficult access into the central arterial cannulation and inadequate catheter position.^[10,11] Advanced vascular disease with tortuous subclavian artery and aortic arch in elderly patients is challenging for successful radial access.^[12] Recent data showed that age was an independent predictor of failed TRA coronary procedures, especially in patients older than 75 years.^[13] In this study, cross-over rates related to vessel tortuosity and occlusion were higher in elderly patients compared to non-elderly patients, but overall cross-over rate was similar in both group. Furthermore, procedural characteristics, such as procedure time, contrast volume and catheter

number used, were not different in elderly group compared to in non-elderly group.

Elderly patients are more likely to suffer from back pain. Patients with transfemoral access should maintain a supine position for extended hours after procedure to achieve hemostasis even with vascular closure device. TRA catheterization eliminates the need for post procedure flat time, and most patients are able to ambulate or change position immediately following the procedure. Comfort for elderly patients is clearly in favor of TRA catheterization.

Many previous studies showed that independent predictor of access site crossover from TRA to transfemoral access is old age.^[13,14] Le, *et al.*^[14] reported that age > 75 years was independent predictor of access site crossover, but also operator experience was also important to determinate TRA success. Hess, *et al.*^[15] addressed 30 to 50 cases would be required to overcome the learning curve. In KOTRI registry, about 90 percent of physicians were experienced TRA operators and experienced operator could overcome anatomical difficulties for TRA. Valsecchi, *et al.*^[16] compared efficacy of TRA by a single operator in patients with age ≥ 70 years to age < 70 years. Although elderly patients have a higher incidence of tortuous vascular access, vascular access success, procedure success, procedural characteristics and complications were not different.^[16] Similarly, Cao, *et al.*^[17] demonstrated that procedural success and complication rates of TRA in over 65 years old patients were comparable with in younger group. To our knowledge, this is the first study that showed similar efficacy and safety of TRA in the oldest patients group (over 80 years old) compared with younger patients by propensity score matched analysis.

The present study has some limitation. This study is a prospective study, but not randomized controlled trials. Thus, there was a possibility of selection bias, but propensity score matched analysis was used to control possible referral. Secondly, access site was chosen by the physicians' decision. This might underestimate procedural failure in the elderly patients. Finally, some missing data in this registry could affect the result.

In conclusion, TRA in elderly patients appears to be as safe and feasible as in non-elderly patients. Complication rates and clinical outcomes in elderly patients who underwent coronary angiography or intervention by radial approach were comparable with those in non-elderly patients.

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