Comparison on the Efficacy and the Safety of Transradial Approach versus Conventional Transfemoral Approach for Cardiac Catheterization Procedures

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Objective: *To compare the efficacy and safety of transradial approach (TR) and conventional transfemoral approach (TF) for cardiac catheterization procedures.*
Material and Method: *The data were collected retrospectively of all patients that received cardiac catheterization at Thammasat University Cardiac Center between September 1, 2010 and August 31, 2011 (the first year of TR approach).*
Results: *Cardiac catheterization was performed on 597 patients. TR approach was performed about one-sixth of all procedures compared to conventional TF approach, 93 (15.58%) vs. 504 (84.42%). Safety of TR approach at the beginning was similar to conventional TF approach including in-hospital complication rate 5.4% vs. 4.6%, p = 0.788, volume of contrast media used 90.63±66.83 vs. 97.89±64.52 milliliters, p = 0.323, radiation exposure defined as median/min-max estimate skin entrance radiation dose 833.35/133.15-8,913.42 vs. 910.00/76.78-13,719.88 mGy, p = 0.599, and dose-area product 63.03/7.87-494.52 vs. 70.85/5.77-829.16 Gy x cm*^{2}*, p = 0.586. The efficacy defined as procedural success rate was significantly higher in the conventional TF approach 90.3% vs. 97.8%, p = 0.001, as well as the procedural time that showed insignificantly longer 54.03±39.40 vs. 47.37±39.86 minutes, p = 0.139. This statistical difference in the procedural success rate was clear only in the first 62 TR. After this learning curve period, the procedural success rate was similar, 96.8% vs. 97.6%, p = 0.575. Both the procedural success rate and the procedural time in TR approach showed trend to achieve better outcomes according to the increasing number of TR procedures; 87.1% vs. 87.1% vs. 96.8%, p = 0.331 and 64.68±51.90 vs. 52.45±31.94 vs. 44.97±29.04 minutes, p = 0.139 in the first 31 vs. the 32*nd *to the 62*nd*, and the 63*rd *to the 93*rd *cases respectively.*
Conclusion: *The safety of the transradial approach for cardiac catheterization procedures was similar to conventional transfemoral approach. The learning curve period was needed but its length is acceptable before the same efficacy rate as the conventional transfemoral procedure was achieved.*

Keywords: *Learning curve, Transradial (TR) cardiac catheterization*

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Transradial (TR) approach for cardiac catheterization was first reported by Lucian Campeau for radial coronary angiography (CAG) in 1989 and first elective radial percutaneous coronary intervention (PCI) by Ferdinand Kiemeneij in 1992[1,2]. Later, there was an increase in the use of TR approach around the world. Regarding from executive summary by the transradial committee of the Society for Cardiac Angiography and Interventions (SCAI), this technique has been gaining acceptance as an alternative to conventional transfemoral (TF) approach and estimated 20% of procedures were performed by this route in worldwide (29% if the US is excluded from the estimate). The countries with the highest rates of TR approach (70-80%) are Norway, Malaysia, and Bulgaria[3]. The efficacy of TR approach, which is defined as procedural success rate, was not different from conventional TF approach in previous review literature[4]. At present, the more complex coronary lesions including chronic total occlusion, anomalous origins of coronary arteries, or primary PCI for STEMI patients were performed PCI by TR approach especially in Asia[5-9], but there is still limited data published in Thailand[10,11]. Safety of TR approach in highly experience operator had been published as superior to conventional TF approach, but the safety of TR approach in learning curve period had

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been seldom published in reviewed literature. The objective of the present study was to compare the efficacy and the safety, especially during the period of the learning curve of transradial approach (TR) and the conventional transfemoral approach (TF) for cardiac catheterization procedures.

Material and Method

The data were collected retrospectively from the registry of all patients who underwent cardiac catheterization at Thammasat University Cardiac Center between September 1, 2010 and August 31, 2011. The patients were divided into two groups, by the access of arterial site for cardiac catheterization according to the operators' decision, to compare efficacy and safety of the procedures. The first group was TR approach and the second group was conventional TF approach. The ethical approval protocol number was MTU-EC-IM-4-154/55.

Definitions

The transradial approach protocol was done in eight steps. 1) Assessment of patient's palmar arch by Allen test, which had to be normal. 2) Local anesthesia was done with 2% Xylocaine 0.5-1 cc at 1 to 2 cm proximal to the radial styloid along the axis of the palpating right radial artery. 3) Cannulation of right radial artery with 20 G x 1¼ inch Medicut puncture catheter. 4) Advance 0.025 inch hydrophilic guidewire. 5) Placement of a long 6F hydrophilic radial sheath with taper introducer over the 0.025 inch guidewire. 6) 3,000 unit Heparin administered immediately after sheath insertion. 7) Standard diagnostic or guiding catheters (JL 3.5 6F for left coronary system and JR 3.5 6F for right coronary system) were advanced into aortic root over 0.035 inch J curve guidewire. 8) After completing the procedure, radial sheath was removed and bleeding was stopped by Terumo band dressing (Terumo Co.).

The transfemoral approach protocol was done in six steps. 1) Local anesthesia was done with 2% Xylocaine 8 to 10 cc at 1 or 2 cm below the inguinal ligament along the axis of the palpating common femoral artery. 2) Cannulation of common femoral artery with 18 G x 2¾ inch puncture needle. 3) Advance the 0.038 inch J curve guidewire. 4) Placement of a 6F femoral sheath with taper introducer over the 0.038 inch J curve guidewire. 5) Standard diagnostic or guiding catheters (JL 4 6F for left coronary system and JR 4 6F for right coronary system or other specific catheters were used depended on the operators) were advanced into aortic root over 0.035 inch J curve guidewire. 6) After completing the procedure, femoral sheath was removed and bleeding was stopped immediately after CAG procedures or six hours later after PCI procedures by manual compression.

The efficacy of procedure was evaluated by procedural success rate and procedural time. The safety of procedure was evaluated by percentage of in-hospital complications including major adverse cardio-cerebrovascular event (MACCE) and non-MACCE, volume of contrast media used, and radiation exposure including fluoroscopic time, estimate skin entrance radiation dose, or the absorbed dose represented by Air kerma and dose-area product (DAP). The MACCE event included myocardial infarction, death, stroke, emergency coronary artery bypass grafting, and repeated PCI at the same site. The non-MACCE included coronary perforation, ventricular fibrillation during procedure, major bleeding or hematoma size >5x5 cm, minor bleeding, and vago-vagal reflex during off sheath. Major bleeding was defined as intracranial, intraocular, or retroperitoneal hemorrhage, or any hemorrhage requiring a transfusion or surgical intervention or those resulted in a hematocrit decreased of greater than 15% or hemoglobin decreased of greater than 5 g/dL. Major hematoma was defined as hematoma of at least 5 cm in diameter at access sites. Procedural time was defined as time from start puncture the access arterial site to time of vascular sheath removal in CAG procedures, suture vascular sheath, or vascular sheath removal and vascular closure devices implantation (in TF approach), or placement of Terumo band dressing (in TR approach) in PCI procedures. Successful procedure was defined as a procedure that resulted in complete contrast media intra-coronary injection in both coronary arterial systems for diagnostic coronary artery disease without complication in CAG procedure or a procedure that resulted in obtaining Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow and residual stenosis of <20% without complication in PCI procedure and no evidence of cross over to another arterial puncture site.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation (SD) or median when appropriate, and discrete variables are expressed as percentages. Differences in the distribution of selected characteristics between patient groups were examined using the Chi-square test for categorical variables.

Differences in continuous variables between study groups were analyzed using either analysis of variance. Two-sample Wilcoxon rank-sum (Mann-Whitney) test was performed when data showed departure from normality. A *p*-value less than 0.05 was considered statistically significant. All statistical data was analyzed by SPSS program for windows version statistics 19.

Results

Five hundred ninety seven patients underwent cardiac catheterization; mean age was 65.11±12.66 years, male 62.3%. Nearly half of them (48.6%) were known case of coronary artery disease (CAD). They composed of previous myocardial infarction (32.1%), previous PCI (14.8%), or previous CABG (1.7%). Most common atherosclerosis risk factor was hypertension (75.4%), followed by dyslipidemia (68.3%), and diabetes (39.6%). Co-incidence of atherosclerosis arterial disease was found in 15.6%, which composed of peripheral arterial disease (5.6%) and known cerebro-vascular accident or transient ischemic attack (10%). Mean baseline creatinine clearance was 52.20±29.73 ml/min, mean left ventricular ejection fraction was 51.38±16.83%, and the percentage of patients who were performed PCI was 37.4%. TR approach was performed in about one-sixth of all procedures compared to conventional TF approach 93 (15.58%) vs. 504 (84.42%) respectively. All demographic data, atherosclerosis risk factors, and percentage of patients who underwent PCI were not different between TR and TF approach except previous PCI, which had higher percentage in TF approach 6.5% vs. 16.3%, $p = 0.016$ as showed in Table 1. Large majority of cardiac catheterization was non-ST elevation acute coronary syndrome (non-ST-ACS) 57.1%, which composed of non-ST elevation myocardial infarction (NSTEMI) (27.6%), unstable angina (UA) (29.5%), heart failure (rule out dilated cardiomyopathy) (13.7%), and chronic stable angina who failed medication therapy (10.7%). Primary PCI for ST elevation myocardial infarction (STEMI) was 5.9%. Two significant different indications for cardiac catheterization between both groups were STEMI 0% vs. 6.9%, $p = 0.003$ and preoperative CAG for cardiac surgery 23.7% vs. 6.5%, $p<0.001$. The result of coronary angiogram showed 66.8% significant CAD, 17.8% minor CAD, and 15.4% normal coronary artery. Significant CAD composed of single vessel disease 26%, double vessel disease 18.2%, triple vessel disease 22.7%, and left main disease 9.3%. All of these findings were not different between group except normal coronary, which was significant higher in TR approach

Table 1. Baseline characteristic data of all patients

	Total (n = 597)	Radial (n = 93)	Femoral (n = 504)	*p*-value
Demographic data				
Age	65.11±12.66	63.20±11.17	65.46±12.90	0.115
Male	372 (62.3%)	59 (63.4%)	313 (62.1%)	0.907
Hight (meters)	1.60±0.09	1.61±0.09	1.60±0.08	0.496
Weight (Kg)	62.66±13.14	64.97±15.22	62.23±12.69	0.065
Previous MI	189 (32.1%)	24 (26.1%)	165 (32.2%)	0.224
Previous PCI	87 (14.8%)	6 (6.5%)	81 (16.3%)	0.016
Previous CABG	10 (1.7%)	0 (0%)	10 (2.0%)	0.373
Atherosclerosis risk factors (n = 589)				
Family history of CAD	93 (15.8%)	16 (17.4%)	77 (15.5%)	0.641
Hypertension	444 (75.4%)	67 (72.8%)	377 (75.9%)	0.514
Dyslipidemia	394 (66.9%)	54 (58.7%)	340 (68.4%)	0.072
Current smoking	92 (15.6%)	9 (9.8%)	83 (16.7%)	0.117
Diabetes	233 (39.6%)	30 (32.6%)	203 (40.8%)	0.164
Known CVA-TIA	59 (10.0%)	6 (6.5%)	53 (10.7%)	0.261
Known PAD	33 (5.6%)	3 (3.3%)	30 (6.0%)	0.457
Creatinine clearance (ml/min)	52.20±29.73	57.66±27.74	51.20±30.00	0.054
LVEF (%) (n = 537)	51.38±16.83	51.32±16.76	51.39±16.87	0.977
No of patients who were performed PCI	223 (37.4%)	27 (29.0%)	196 (38.9%)	0.080

MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CVA = cerebrovascular accident; TIA = transient ischemic attack; PAD = peripheral artery disease; LVEF = left ventricular ejection fraction

Table 2. Comparison of indications and results of coronary angiogram (CAG) by transradial approach (TR) at the beginning versus conventional transfemoral approach (TF)

Indication for coronary angiogram	Total (n = 597)	Radial (n = 93)	Femoral (n = 504)	*p*-value
STEMI	35 (5.9%)	0 (0%)	35 (6.9%)	0.003
NSTEMI	165 (27.6%)	26 (28.0%)	139 (27.6%)	1.000
Unstable angina	176 (29.5%)	23 (24.7%)	153 (30.4%)	0.322
Chronic stable angina	64 (10.7%)	5 (5.4%)	59 (11.7%)	0.098
Asymptomatic CAD	20 (3.4%)	4 (4.3%)	16 (3.2%)	0.534
Preoperative CAG	55 (9.2%)	22 (23.7%)	33 (6.5%)	<0.001
Heart failure (rule out DCM)	82 (13.7%)	13 (14.0%)	69 (13.7%)	1.000
Results of coronary angiogram	**Total (n = 578)#**	**Radial (n = 90)**	**Femoral (n = 488)**	***p*-value**
Normal coronary arteries	89 (15.4%)	21 (23.3%)	68 (13.9%)	0.037
Non-obstructive coronary artery	103 (17.8%)	13 (14.4%)	90 (18.4%)	0.454
Single vessel disease	150 (26.0%)	21 (23.3%)	129 (26.4%)	0.602
Double vessel disease	105 (18.2%)	15 (16.7%)	90 (18.4%)	0.767
Triple vessel disease	131 (22.7%)	20 (22.2%)	111 (22.7%)	1.000
Left main disease	54 (9.3%)	4 (4.4%)	50 (10.2%)	0.112

DCM = dilated cardiomyopathy
# Exclude 19 elective PCI cases

group, 23.3% vs. 13.9%, $p = 0.037$ as showed in Table 2. Overall, the safety of cardiac catheterization procedures via TR approach at the beginning was not different from conventional TF approach, which included all in-hospital complications 5.4% vs. 4.6%, $p = 0.788$, MACCE 4.3% vs. 1.8%, $p = 0.13$, non-MACCE 1.1% vs. 2.8%, $p = 0.487$, volume of contrast media used 90.63±66.83 vs. 97.89±64.52 ml, $p = 0.323$, median/min-max fluoroscopic time 11.14/1.53-95.10 vs. 8.36/1-183.52 minutes, $p = 0.006$, estimate skin entrance radiation dose 833.35/133.15-8,913.42 vs. 910.00/76.78-13,719.88 mGy, $p = 0.599$, and dose-area product 63.03/7.87-494.52 vs. 70.85/5.77-829.16 Gy x cm^2, $p = 0.586$. Overall, the efficacy showed superior in conventional TF approach, which was defined as significant higher procedural success rate, 90.3% vs. 97.8%, $p = 0.001$ and insignificant longer in procedural time, 54.03±39.40 vs. 47.37±39.86 minutes, $p = 0.139$, as showed in Table 3.

Discussion

The advantage of TR approach over conventional TF approach is the lower risk of access site complication including bleeding or hematoma, which is the most common complication of cardiac catheterization[12,13]. Reducing incidence of bleeding complications may be related to lower mortality[14,15]. Patients needing warfarin therapy can receive cardiac catheterization procedures safely via this route without discontinuing medication[16,17]. The patients can mobilize immediately after the procedure is finished, but in TF approach, they need at least six hours to stay in supine position after CAG and at least 10 to 12 hours after PCI to stop bleeding. The earlier mobilization is more comfortable, so it is suitable for the elderly, the obese, or patient with chronic severe back pain that cannot stay long in supine position. Same day discharge for uncomplicated PCI via TR approach is feasible and safe[18]. These are reflected in improved patient's satisfaction[19,20]. However, at the beginning, the TR approach had high crossover rate to TF approach[21] and needed a learning curve to achieve the same efficacy rate as conventional TF approach. This is because it is technically more difficult due to smaller vessel diameter, has more incidence of spasm, has more tortuosity and more anatomical variation of radial artery than the femoral artery[22,23]. The objective of the present study was to compare the efficacy and the safety, especially during the first period of the learning curve of transradial approach (TR) to the conventional transfemoral approach (TF) for cardiac catheterization procedures.

Almost all baseline demographic data, atherosclerosis risk factors, and indications for cardiac catheterization of patients in the present study were similar to previous literatures[11,24]. Common

Table 3. Comparison safety and efficacy of transradial approach at the beginning versus conventional transfemoral approach in overall patients

	Total (n = 597)	Radial (n = 93)	Femoral (n = 504)	*p*-value
Safety				
All in-hospital complications	28 (4.7%)	5 (5.4%)	23 (4.6%)	0.788
MACCE	13 (2.2%)	4 (4.3%)	9 (1.8%)	0.130
Death	2 (0.3%)	0 (0%)	2 (0.4%)	1.000
Periprodedural MI (CK-MB >5 times)	10 (1.7%)	4 (4.3%)	6 (1.2%)	0.055
Emergency CABG	0 (0%)	0 (0%)	0 (0%)	-
Repeated PCI at the same site	1 (0.2%)	0 (0%)	1 (0.2%)	1.000
Stroke	0 (0%)	0 (0%)	0 (0%)	-
Non MACCE	15 (2.5%)	1 (1.1%)	14 (2.8%)	0.487
Coronary perforation	1 (0.2%)	0 (0%)	1 (0.2%)	1.000
VF	1 (0.2%)	0 (0%)	1 (0.2%)	1.000
Major bleeding or hematoma size >5x5 cm	5 (0.8%)	1 (1.1%)*	4 (0.8%)	0.573
Minor bleeding	4 (0.7%)	0 (0%)	4 (0.8%)	1.000
Vago-vagal reflex during off sheath	3 (1.4%)	0 (0%)	3 (1.6%)	1.000
Volume of contrast media used (ml)	96.75±64.88	90.63±66.83	97.89±64.52	0.323
Radiation exposure				
Median/min-max fluoroscopic time (min)	8.50/ 1.00-183.52	11.14/ 1.53-95.10	8.36/ 1.00-183.52	0.006
Median/min-max estimate skin entrance radiation dose (mGy)	886.23/ 76.78-13,719.88	833.35/ 133.15-8,913.42	910.00/ 76.78-13,719.88	0.599
Median/min-max dose-area product (Gy x cm^2)	67.82/ 5.77-829.16	63.03/ 7.87-494.52	70.85/ 5.77-829.16	0.586
Efficacy				
Procedural success rate	577 (96.6%)	84 (90.3%)	493 (97.8%)	0.001
Procedural time (min)	48.42±39.83	54.03±39.40	47.37±39.86	0.139
Procedural success rate excluded 6 cases which crossed over to TF	577 of 591 (97.6%)	84 of 87 (96.6%)	493 of 504 (97.8%)	0.450

MACCE = major adverse cardio-cerebrovascular event; CK-MB = creatine kinase-myocardial band; VF = ventricular fibrillation
* Radial artery perforation

atherosclerosis risk factors were hypertension, dyslipidemia, and diabetes. Large majority of cardiac catheterization indication was non-STE-ACS. The percentage of significant CAD to overall coronary angiographic finding was slightly higher than previous published data in Thailand 66.8% vs. 59%[11] and Western country 66.8% vs. 60.9%[24]. The procedural success rate was high and similar to contemporary results from other studies 96.6% vs. 91 to 98%[25-30]. The proportion of TR approach and TF approach in the present study was about one-sixth of overall procedures (15.58%), which was slightly lower than data from total worldwide 15.58% vs. 22%, and much lower than data from Asia 15.58% vs. 42%[3]. However, nowadays, there is still unknown about the proportion of TR cardiac catheterization procedure in Thailand. The baseline characteristic data, the indication for cardiac catheterization, and the result of coronary angiogram were not different between both groups because the present study collected data retrospectively at the beginning of TR approach procedure, so the data were collected selectively with only uncomplicated cases and avoided complex PCI cases to achieve successful TR approach procedure. Therefore, the previous PCI was only patients' baseline characteristic data significantly higher TF approach group 6.5% vs. 16.3%, $p = 0.016$. In addition, it still influenced the indication for cardiac catheterization and the result of coronary angiogram, which showed significant higher primary PCI for STEMI procedures in TF approach group 0% vs. 6.9%, $p = 0.003$, higher preoperative CAG for cardiac surgery 23.7% vs. 6.5%, $p<0.001$, and higher normal coronary artery angiographic finding 23.3% vs. 13.9%, $p = 0.037$ in TR approach group as showed in Table 1, 2.

Even though most patients' baseline characteristic data were different, the percentage of patients who underwent PCI was not significantly different in both groups 29% vs. 38.9%, $p = 0.08$. The safety of cardiac catheterization showed insignificantly different between both groups, same as previous literatures[31,32] including all in-hospital complications 5.4% vs. 4.6%, $p = 0.788$, MACCE 4.3% vs. 1.8%, $p = 0.13$, non-MACCE 1.1% vs. 2.8%, $p = 0.487$, volume of contrast media used 90.63±66.83 vs. 97.89±64.52 ml, $p = 0.323$, median/min-max estimate skin entrance radiation dose 833.35/133.15-8,913.42 vs. 910.00/76.78-13,719.88 mGy, $p = 0.599$, and dose-area product 63.03/7.87-494.52 vs. 70.85/5.77-829.16 Gy x cm^2, $p = 0.586$. Median fluoroscopic time showed significantly longer in TR approach group 11.14/1.53-95.10 vs. 8.36/1-183.52 minutes, $p = 0.006$, as showed in Table 3. Nevertheless, the outcomes of the present study cannot declare the advantage of TR approach, especially the lower incidence of bleeding or hematoma at the access arterial site[12]. This is because the volume of sample size in TR approach group was too small. In addition, the present study collected TR approach data in low experience operator, so there was one case who had unexpected radial artery rupture and developed hematoma at forearm that made the percentage of this complication similar to TF approach 1.1% vs. 0.8%, $p = 0.573$. In this case, after managed by external compression and observed clinical, there was no serious complication or compartment syndrome. The present data showed that even though at the beginning of TR approach procedure, the safety was still as same as conventional TF approach. The efficacy of TR approach showed significant lower than TF approach group, which defined as the procedural success rate 90.3% vs. 97.8%, $p = 0.001$ and insignificant longer procedural time 54.03±39.40 vs. 47.37±39.86 minutes, $p = 0.139$. Nine cases failed the TR approach procedure. The main cause of TR procedural failure related to TR approach procedural technique. They needed cross over to TF approach procedures, which composed of five cases (55.56%) of radial artery puncture failure and one case (11.11%) that failed to engage the diagnosis catheter (JL 3.5) to the left main's ostium. These six crossover cases were performed TF cardiac catheterization successfully. The other three TR failure cases (33.33%) related to PCI procedural technique, which composed of two cases (22.22%) failed because they could not pass the coronary wire through the heavy calcified lesions, one case (11.11%) failed because the smallest balloon (1.25 mm diameter) could not follow the coronary wire through severe calcified stenosis lesion. If the six cross over cases were excluded, the procedural success rate was not different to TF approach group 96.6% vs. 97.8%, $p = 0.45$ as showed in Table 3. However, the procedural success rate of TR approach at the beginning was still high and similar to contemporary results from other studies 90.3% vs. 91 to 98%[25-30]. According to data from previous literatures, a learning curve period of TR approach at the beginning was needed to achieve the procedural success rate as same as conventional TF approach[22,23]. The patients in both groups were divided into three subgroups by the sequence number of procedures, the first one-third, the second one-third, and the third one-third subgroup for comparing safety and efficacy to each other. The procedural success rate showed statistically superior in conventional TF approach just only in the first and second subgroups 87.1% vs. 97.6%, $p = 0.022$ and 87.1% vs. 98.2%, $p = 0.012$. After the learning curve period of first 62 TR approach procedures, the procedural success rate was not different 96.8% vs. 97.6%, $p = 0.575$. The procedural time showed insignificantly different about 13 minutes longer in TR approach after the first subgroup 64.68±51.90 vs. 51.57±42.48 minutes, $p = 0.130$. After passed the first 31 TR approach procedures, the procedural time was similar to conventional TF approach 52.45±31.94 vs. 49.27±37.06 minutes, $p = 0.655$ in the second subgroup and 44.97±29.04 vs. 41.34±39.41 minutes, $p = 0.626$ in the third subgroup. However, the safety of procedure was not statistically different in all three subgroups as showed in Table 4. The present data supported that learning curve period for starting cardiac catheterization via TR approach at the beginning was needed to achieve the same efficacy rate as conventional TF approach; the safety of TR approach in learning curve period was not statistically different from conventional TF approach.

The efficacy and safety of TR approach had also shown relationship between increase volume of TR approach procedures and decrease different procedure-related parameters that corresponding to previous literature[33]. The procedural success rate showed increase insignificantly from 87.1% to 96.8%, $p = 0.145$. Other procedural-related parameters decreased insignificantly including procedural time from 64.68±51.90 to 52.45±31.94 to 44.97±29.04 minutes, $p = 0.139$, volume of contrast media used from 98.23±78.00 to 87.23±61.67 to 86.45±60.97 ml, $p = 0.744$, median/min-max fluoroscopic time from 12.84/2.25-95.10 to 9.26/2.52-38.24 to 9.38/1.53-43.17 minutes, estimate skin entrance radiation dose from

Table 4. Comparison safety and efficacy of transradial approach at the beginning versus conventional transfemoral approach according to the increasing number of procedures

	The first one-third subgroup (n = 199)			The second one-third subgroup (n = 199)			The third one-third subgroup (n = 199)		
	TR (n = 31)	TF (n = 168)	*p*-value	TR (n = 31)	TF (n = 168)	*p*-value	TR (n = 31)	TF (n = 168)	*p*-value
Safety									
All in-hospital complications	3 (9.7%)	8 (4.8%)	0.382	1 (3.2%)	7 (4.2%)	1.000	1 (3.2%)	8 (4.8%)	1.000
MACCE	2 (6.5%)	1 (0.6%)	0.064	1 (3.2%)	7 (4.2%)	1.000	1 (3.2%)	1 (0.6%)	1.000
Major bleeding or hematoma size >5x5 cm	1 (3.2%)*	2 (1.2%)	0.402	0 (0%)	0 (0%)	-	0 (0%)	2 (1.2%)	1.000
Volume of contrast media used (ml)	98.23±78.00	105.75±98.23	0.548	87.23±61.67	98.10±63.03	0.377	86.45±60.97	89.82±68.59	0.799
Median/min-max fluoroscopic time (min)	12.84/ 2.25-95.10	10.56/ 1.03-132.48	0.133	9.26/ 2.52-38.24	10.78/ 1.03-125.58	0.175	9.38/ 1.53-43.17	5.49/ 1.00-183.52	0.074
Median/min-max estimate skin entrance radiation dose (mGy)	933.87/ 175.59-8,913.42	1,075.11/ 112.53-10,218.88	0.840	794.32/ 253.73-4,570.16	1,093.84/ 122.09-13,719.88	0.450	737.84/ 133.15-4,536.19	657.75/ 76.78-9,910.43	0.891
Median/min-max dose-area product (Gy x cm^2)	71.50/ 13.73-494.52	80.41/ 9.52-548.03	0.818	59.75/ 18.83-357.22	84.20/ 7.45-829.16	0.508	57.89/ 7.87-320.26	51.22/ 5.77-793.99	0.973
Efficacy									
Procedural success rate	27 (87.1%)	164 (97.6%)	0.022	27 (87.1%)	165 (98.2%)	0.012	30 (96.8%)	164 (97.6%)	0.575
Procedural time (min)	64.68±51.90	51.57±42.48	0.130	52.45±31.94	49.27±37.06	0.655	44.97±29.04	41.34±39.41	0.626

* Radial artery perforation

933.87/175.59-8913.42 to 794.32/253.73-4570.16 to 737.84/133.15-4536.19 mGy, and DAP from 71.50/13.73-494.52 to 59.75/18.83-357.22 to 57.89/7.87-320.26 Gy x cm^2 as showed in Fig. 1. The significant improvement may need a larger sample size. It is reasonable to start a TR cardiac catheterization training program parallel to a conventional TF approach because, first, it needs short learning curve period, second, the procedural safety in the learning curve period is similar to conventional TF approach, and third, the higher TR operator volume has higher safety and efficacy of procedure. Performing TR cardiac catheterization with high experience may achieve the same efficacy and a higher procedural safety than conventional TF approach, especially in the access arterial site complications.

Conclusion

The safety of the transradial approach for cardiac catheterization procedures was similar to conventional transfemoral approach. A learning curve period is needed to achieve the same efficacy rate as the conventional transfemoral procedure but its length is acceptable.

Limitations

1) The results of a single center study cannot be generalized. 2) This is a retrospective study that collected data at the beginning of TR approach procedures, so some data were collected selectively and there were some missing data. 3) CAG and PCI procedures should be compared separately because the safety and efficacy of the procedures are different. Future study is needed to compare these clinical outcomes.

What is already known on this topic?

Transradial approach for cardiac catheterization has been gaining acceptance as an alternative to conventional transfemoral approach due to the lower complication risk including bleeding or hematoma, which is the most common complication. Learning curve period in TR approach was needed to achieve the same efficacy rate as conventional transfemoral approach. This is because it is technically more difficult due to smaller blood vessel diameter, more incidences of spasm, more tortuosity, and more anatomical variation of radial artery than femoral artery. Safety of TR approach in high experience operator had been published as superior to conventional TF approach, but information on safety of TR approach

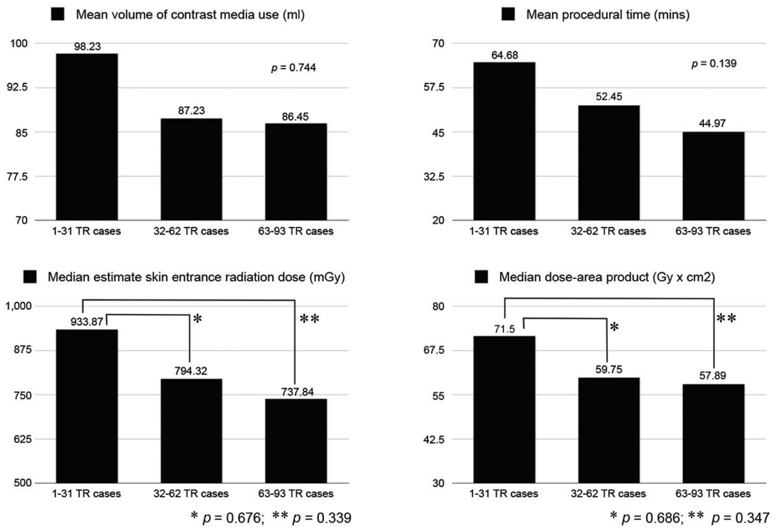

Fig. 1 Safety and efficacy of transradial approach according to the increasing number of procedures.

in learning curve period had been limited in review literatures.

What this study adds?

Safety of transradial approach at the beginning for cardiac catheterization procedures was not different from conventional transfemoral approach. Learning curve period was needed but was short to achieve the same efficacy rate as conventional transfemoral procedures. It is reasonable to start transradial cardiac catheterization training program parallel to conventional transfemoral approach because it needs short learning curve period, the procedural safety in learning curve period is similar to conventional transfemoral approach, and the higher transradial operator volume increase the safety and efficacy of the procedure. Performing transradial cardiac catheterization with high experience can achieve better clinical outcomes.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบประสิทธิภาพและความปลอดภัยระหว่างการทำหัตถการสวนหัวใจผ่านทางหลอดเลือด radial artery ในระยะเริ่มต้นกับการสวนหัวใจโดยวิธีมาตรฐานผ่านทางหลอดเลือด femoral artery

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วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบประสิทธิภาพและความปลอดภัยระหว่างการทำหัตถการสวนหัวใจผ่านทางหลอดเลือด radial artery ในระยะเริ่มต้นกับการสวนหัวใจโดยวิธีมาตรฐานผ่านทางหลอดเลือด femoral artery*

วัสดุและวิธีการ: *เป็นการศึกษาแบบเก็บข้อมูลย้อนหลังในผู้ป่วยโรคหัวใจทุกรายที่ได้รับการตรวจวินิจฉัยและรักษาโดยการสวนหัวใจที่โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ตั้งแต่วันที่ 1 กันยายน พ.ศ. 2553 ถึง 31 สิงหาคม พ.ศ. 2554*

ผลการศึกษา: *มีผู้ป่วยทั้งหมด 597 ราย เข้ารับการตรวจวินิจฉัยและรักษาโรคหัวใจโดยการสวนหัวใจ 93 ราย ได้รับการสวนหัวใจผ่านทางหลอดเลือด radial artery คิดเป็นร้อยละ 15.58 และ 504 ราย ได้รับการสวนหัวใจผ่านทาง femoral artery คิดเป็นร้อยละ 84.42 ความปลอดภัยของการทำหัตถการสวนหัวใจผ่านทาง radial artery ในระยะเริ่มต้นไม่แตกต่างจากการทำหัตถการผ่านทางหลอดเลือด femoral artery กล่าวคือ อัตราการเกิดภาวะแทรกซ้อนทั้งหมดในโรงพยาบาลร้อยละ 5.4 กับ 4.6, p = 0.788 ปริมาณการใช้สารทึบรังสี 90.63±66.83 vs. 97.89±64.52 มิลลิลิตร, p = 0.323 การสัมผัสกับรังสีซึ่งประกอบด้วย median/min-max estimate skin entrance radiation dose 833.35/133.15-8,913.42 vs. 910.00/76.78-13,719.88 mGy, p = 0.599 และ dose-area product 63.03/7.87-494.52 vs. 70.85/5.77-829.16 Gy x cm^2, p = 0.586ประสิทธิภาพของการทำหัตถการซึ่งประกอบด้วย ร้อยละความสำเร็จในการทำหัตถการผ่านหลอดเลือด radial artery ต่ำกว่าการทำหัตถการผ่านหลอดเลือด femoral artery อย่างมีนัยสำคัญทางสถิติ 90.3 vs. 97.8, p = 0.001 ซึ่งความแตกต่างนี้พบได้ในการทำหัตถการผ่านทาง radial artery 62 รายแรกเท่านั้น หลังจากนั้นร้อยละความสำเร็จในการทำหัตถการไม่แตกต่างกันคือ 96.8 vs. 97.6, p = 0.575 นอกจากนี้เมื่อเปรียบเทียบจำนวนการทำหัตถการผ่านทาง radial artery ที่เพิ่มขึ้นจาก 31 หัตถการแรกกับหัตถการที่ 32 ถึง 62 และหัตถการที่ 63 ถึง 93 ยังพบความสัมพันธ์ที่มีแนวโน้มเพิ่มขึ้นของร้อยละความสำเร็จในการทำหัตถการคือ 87.1 vs. 87.1 vs. 96.8, p = 0.331 และความสัมพันธ์ที่มีแนวโน้มลดลงของระยะเวลาในการทำหัตถการคือ 64.68±51.90 vs. 52.45±31.94 vs. 44.97±29.04 นาที, p = 0.139 ตามลำดับ*

สรุป: *ความปลอดภัยของการทำหัตถการสวนหัวใจผ่านทางหลอดเลือด radial artery ในระยะเริ่มต้น ไม่แตกต่างจากการทำหัตถการสวนหัวใจโดยวิธีมาตรฐาน ช่วงระยะในการฝึกฝนการทำหัตถการในระยะเริ่มต้นเป็นสิ่งจำเป็นแต่ใช้เวลาไม่นาน เพื่อให้ได้ประสิทธิภาพในการรักษาเทียบเท่ากับการทำหัตถการสวนหัวใจผ่านทางหลอดเลือด femoral artery*