DOI: 10.1111/j.1540-8183.2011.00717.x

ACUTE CORONARY SYNDROME

Reducing Needle-To-Balloon Time by Using a Single Guiding Catheter during Transradial Primary Coronary Intervention

KEON-WOONG MOON, M.D., PH.D, JI-HOON KIM, M.D., JU-YOUN KIM, M.D., MI-HYANG JUNG, M.D., GEE-HEE KIM, M.D., KI-DONG YOO, M.D., PH.D., and CHUL-MIN KIM, M.D., PH.D.

From the Department of Internal Medicine, St. Vincent's Hospital, The Catholic University of Korea, Suwon, South Korea

Objectives and Background: *It is unknown whether using a single guiding catheter for both nonculprit and culprit vessel angiography and intervention during transradial primary percutaneous coronary intervention (PCI) is feasible.*
Methods: *This single-center study enrolled 242 consecutive patients with ST segment elevation myocardial infarction (STEMI) who received primary PCI. Among them, 102 patients received primary PCI via transfemoral approach (TFI), 109 patients received primary PCI via transradial approach using conventional technique (Conventional TRI), and 31 underwent primary TRI using a single guiding catheter (Single Guiding TRI). The catheter used for this purpose was 6 Fr RM® 3.5 guiding catheter.*
Results: *Using a single guiding catheter, both coronary artery angiograms and intervention were successful in 30 of 31 patients (96.7%). Needle-to-balloon time (from puncture to first balloon) and door-to-balloon (D2B) time were similar between TFI and Conventional TRI groups and significantly lower in the Single Guiding TRI group (13.8 [TFI] and 14.1 [Conventional TRI] vs. 7.6 minutes, $P < 0.001$; 89.5 [TFI] and 91.0 [Conventional TRI] vs. 68.5 minutes, $P = 0.008$, respectively), whereas proportion of patients achieving D2B time within 90 minutes increased significantly in the Single Guiding TRI group from 51.0% for TFI and 49.5% for Conventional TRI to 74.2% ($P = 0.023$).*
Conclusions: *Primary transradial PCI using a single guiding catheter is feasible and highly successful and might allow timely restoration of blood flow in infarct-related artery.* (J Interven Cardiol 2012;25:330–336)

Introduction

Early reperfusion therapy is essential in the treatment of patients with ST segment elevation myocardial infarction (STEMI), with primary percutaneous coronary intervention (PCI) when performed in a timely fashion, being preferred over fibrinolytic therapy as reperfusion strategy. The 2004 American College of Cardiology/American Heart Association (ACC/AHA) STEMI Guidelines[1] recommended that the door-to-balloon (D2B) time be less than 90 minutes. D2B time consists of door-to-needle time (from emergency department [ED] to puncture) and needle-to-balloon (N2B) time (from puncture to first balloon inflation). Although numerous studies have attempted to reduce "system delay" or door-to-needle time in primary PCI patients by using, for example, prehospital diagnosis,[2] prehospital activation of the catheterization laboratory and development of primary PCI protocol,[3] or new performance processes,[4] no published study to the best of our knowledge has focused on "primary PCI procedure itself" or N2B time.

This study was performed to determine feasibility and efficacy of using a single guiding catheter during transradial primary PCI (primary TRI). During elective transradial angiography and intervention, using a single catheter for left and right coronary diagnostic and PCI procedures is an attractive idea, with

Address for reprints: Ki-Dong Yoo, M.D., Department of Internal Medicine, St. Vincent's Hospital, #93–6, Ji-dong, Paldal-ku, Suwon, Gyunggi-do, 442–723, South Korea. Fax: 82–31-247–7139; e-mail: yookd@catholic.ac.kr

potentially less procedure and fluoroscopy time, lower costs, and diminished radial artery spasm.[5–7] During primary TRI, using a single guiding catheter for both nonculprit and culprit vessel angiography and intervention has potential to reduce N2B and D2B times and to achieve timely restoration of blood flow of infarct-related artery.

Materials and Methods

Study Population. This study was conducted at a University Hospital with an ED with more than 20,000 visits annually. Between March 2009 and March 2011, all patients with acute STEMI within 12 hours from chest pain onset and who received primary PCI were enrolled. The operators were interventional cardiologists who had performed over 500 cases of transradial approach (TRI). Until October 2010, selection of vascular access route and diagnostic and guiding catheter was left to the discretion of the operator; however, since January 2011, a 6-Fr RM® 3.5 guiding catheter (Jungsung Medical, Songnam, South Korea) was used as a default catheter during TRI. Study protocol was approved by the Institutional Review Board of St.Vincent's Hospital (IRB No. VC11RISI0055), and all patients provided written informed consent.

PCI Procedure. After local anesthesia (1 mL of lidocaine 2%), the radial artery was punctured with a 20-gauge needle. A 0.021-inch straight tip guidewire was introduced, followed by insertion of a 6-Fr radial sheath (7 cm, Terumo Co., Tokyo, Japan). After injection of a solution containing 2,500 IU of heparin and 200 μg of nitroglycerin, retrograde radial angiography was performed through the radial sheath. In the transfemoral approach group (TFI group) and transradial approach with conventional technique group (Conventional TRI group), nonculprit angiography was performed using a 4–6 Fr diagnostic catheter of operator's choice and culprit angiography then was performed using same diagnostic catheter or other diagnostic/guiding catheter at the operator's discretion. In the transradial approach using a single guiding catheter group (Single Guiding TRI group), both nonculprit and culprit vessel angiogram and intervention was performed using a single guiding catheter. Time interval from puncture to first balloon inflation or insertion of thrombus aspiration device was recorded as N2B time. To assess the effects of using a single guiding catheter, the N2B time was subdivided into 3 intervals which were compared: (1) nonculprit angiogram: from puncture to nonculprit vessel angiogram, (2) culprit angiogram: from nonculprit angiogram to culprit angiogram, and (3) first balloon: from culprit angiogram to first balloon inflation or insertion of thrombus aspiration device. Fluoroscopy time and contrast volume used were recorded. Proportions of patients achieving D2B time within 60 minutes and within 90 minutes were compared among 3 groups. Data abstracted from medical records included patients demographics, risk factors, laboratory results, and left ventricular ejection fraction by echocardiography performed the day after primary PCI.

Statistical Analysis. Analyses were performed using R 2.11.1 statistical software.[8] Categorical variables are described as frequencies, whereas continuous variables are reported as median and interquartile ranges. Number of treated lesions is presented as mean and standard deviation. Fisher's exact test or Pearson's Chi-square test with Yates' continuity correction was used to compare categorical variables among 3 groups, whereas one-way analysis of variance (ANOVA) test and Kurskal–Wallis test were used to compare continuous variables. To adjust multiplicity, Tukey's multiple comparisons procedure was used for ANOVA model and Holm's step-down procedure was used for Kurskal–Wallis test. Boxplots are presented comparing N2B and D2B times among 3 groups.

Results

Baseline Clinical Characteristics and In-Hospital Outcome. A total of 242 patients with acute STEMI presented to the ED during study period. Because this study was an all-comer study, all patients were included. Median age was 62 (interquartile range: 53–70) years and 73.6% were men. Of these, 102 patients received primary PCI via TFI group, 109 patients received primary PCI via Conventional TRI group, and 31 underwent primary TRI using a Single Guiding TRI group. Table 1 summarizes the baseline clinical characteristics and in-hospital outcomes. Patients in the TFI group were older than those in the Single Guiding TRI group and more female patients were included. Patients requiring intraaortic balloon pump (IABP) support or postcardiopulmonary resuscitation were more likely included in the TFI group ($P = 0.002$ and $P = 0.045$, respectively). Three patients in the Conventional TRI group required crossover to the femoral artery due to excessive

Table 1. Clinical Characteristics and In-Hospital Outcome of All Acute ST segment Elevation Myocardial Infarction Patients According to Interventional Strategy

	TFI (N = 102)	Conventional TRI (N = 109)	Single Guiding TRI (N = 31)	P Value
Age (years)	63 (57–71)	61 (52–70)	55 (49–67)	0.019
Male	66 (64.7%)	88 (80.7%)	24 (77.4%)	0.026
Diabetes mellitus	36 (35.3%)	31 (28.4%)	14 (45.2%)	0.192
Current smoker	48 (47.1%)	61 (60.0%)	18 (58.1%)	0.347
CVA history	5 (4.9%)	6 (5.5%)	4 (12.9%)	0.249
IABP support	16 (15.7%)	3 (2.8%)	1 (3.2%)	0.002
ECMO support	3 (2.9%)	0 (0.0%)	0 (0.0%)	0.186
After CPR	11 (10.8%)	2 (1.8%)	1 (3.2%)	0.045
Cross-over	1 (1.0%)	3 (2.8%)	1 (3.2%)	0.543
Procedural success	102 (100.0%)	106 (97.5%)	30 (96.8%)	0.236
Retroperitoneal hemorrhage	1 (1.0%)	0 (0.0%)	0 (0.0%)	0.550
Groin hematoma	4 (3.9%)	0 (0.0%)	0 (0.0%)	0.074
Bleeding requiring transfusion	3 (2.9%)	0 (0.0%)	0 (0.0%)	0.186
Death from hemorrhage	1 (1.0%)	0 (0.0%)	0 (0.0%)	0.550
All bleeding complications	6 (5.9%)	0 (0.0%)	0 (0.0%)	0.014
In-hospital death	5 (4.9%)	0 (0.0%)	0 (0.0%)	0.040

Values in parentheses indicate interquatile range.
TFI = transfemoral intervention; TRI = transradial intervention; CVA = cerebrovascular accident;
IABP = intraaortic balloon pump; ECMO = extracorpreal membrane oxygenator; CPR = cardiopulmonary resuscitation.

Table 2. Procedural Characteristics of All Acute ST segment Elevation Myocardial Infarction Patients According to Interventional Strategy

	TFI (N = 102)	Conventional TRI (N = 109)	Single Guiding TRI (N = 31)	P Value
Culprit vessel				
Left main	7 (6.9%)	3 (2.8%)	2 (6.5%)	–
Left anterior descending	52 (51.0%)	55 (50.5%)	19 (61.3%)	0.306
Left circumflex	7 (6.9%)	15 (13.8%)	1 (3.2%)	–
Right coronary	36 (35.3%)	36 (33.0%)	9 (29.0%)	–
Needle-to-balloon time (minutes)	13.8 (9.5–18.0)	14.1 (10.5–19.4)	7.6 (6.2–11.4)	0.000
Nonculprit angiogram	2.8 (1.2–4.5)	2.2 (1.4–3.1)	1.6 (1.4–2.1)	0.258
Culprit angiogram	3.1(2.3–4.0)	3.1 (1.4–4.5)	1.1 (0.5–2.7)	0.000
First balloon	7.0 (3.7–10.5)	8.0 (5.0–12.9)	4.8 (3.3–6.7)	0.001
Door-to-balloon time (minutes)	89.5 (74–114)	91 (68–112)	68.5 (49–104)	0.008
D2B $\leq$ 60 minutes	15 (14.7%)	18 (16.5%)	12 (40.0%)	0.008
D2B $\leq$ 90 minutes	52 (51.0%)	54 (49.5%)	23 (74.2%)	0.043
D2B $\leq$ 120 minutes	78 (76.5%)	85 (78.0%)	28 (90.3%)	0.240
Number of treated lesion	1.3 ± 0.8	1.3 ± 0.7	1.2 ± 0.5	0.497
Fluoroscopy time (minutes)	11.8 (8.5–17.3)	14.2 (10.1– 22.2)	10.0 (6.3–14.5)	0.004
Contrast volume (mL)	200 (144–250)	198 (155–250)	170 (147–214)	0.345
CPK peak (U/L)	1995 (887–3,586)	1816 (850–3,211)	1,380 (874–3,872)	0.069
CK-KB peak (mg/mL)	147.9 (55.6–314.3)	156.9 (50.6–248.9)	126.3 (47.7–226.7)	0.548
Ejection fraction (%)	54.0 (44.3–60.0)	55.5 (47.2–59.3)	54.6 (48.9–58.5)	0.421

Values in parentheses indicate interquatile range.
TFI = transfemoral intervention; TRI = transradial intervention; D2B = Door-to-balloon.

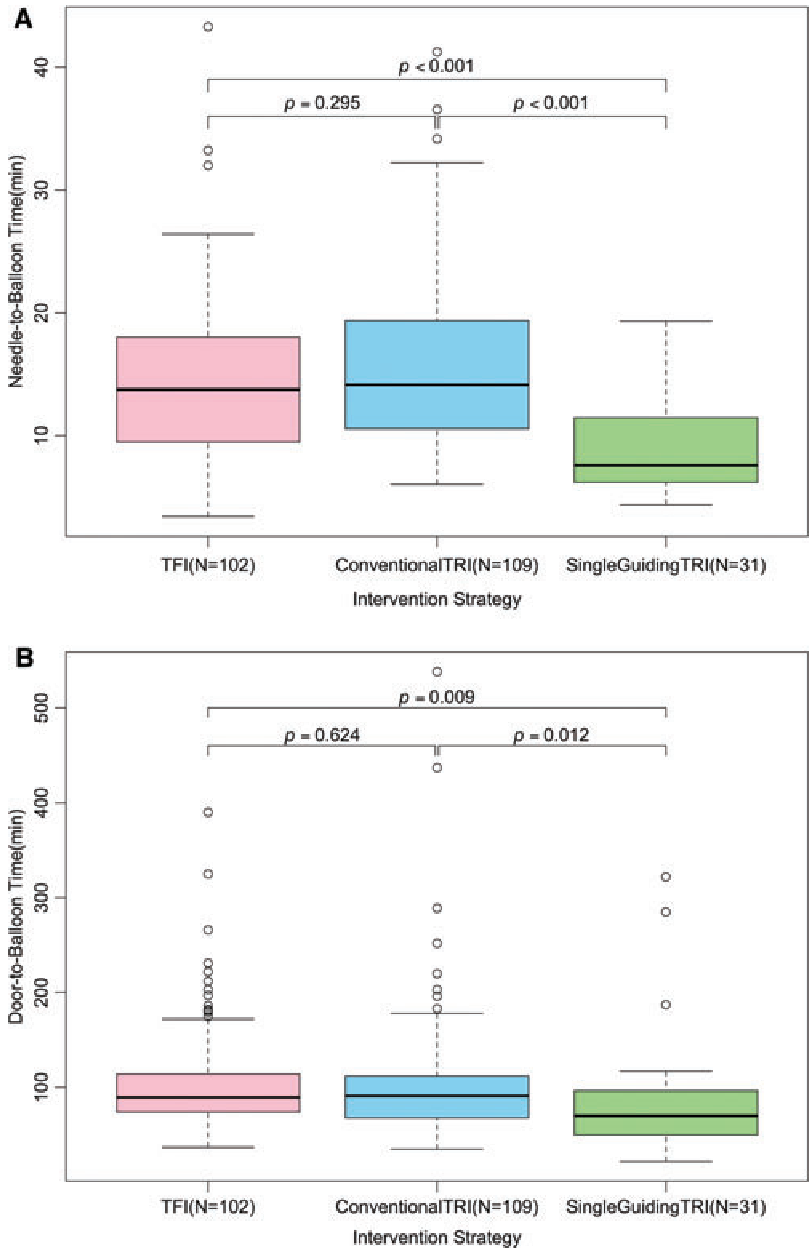

Figure 1. Needle-to-balloon time (A) and door-to-needle time (B) according to intervention strategy

tortuosity of subclavian artery (2 patients) or small diameter of radial artery (1 patient). One patient in TFI group was switched to radial approach after IABP support. One patient in Single Guiding TRI group required additional guiding catheter (JL3.5) for engagement of left coronary artery and intervention. All bleeding complications and in-hospital death rates were higher in the TFI group ($P = 0.014$ and $P = 0.040$, respectively).

Procedural Characteristics. Table 2 summarizes procedural characteristics. "Culprit" vessel location and number of treated lesions were similar among all 3 groups. N2B and D2B times were similar between TFI and Conventional TRI groups. In the Single Guiding TRI group, N2B and D2B times were significantly reduced (N2B time: 13.8 [TFI] and 14.1 [Conventional TRI] vs. 7.6 minutes, $P < 0.001$: and D2B time: 89.5 [TFI] and 91.0 [Conventional TRI] vs.

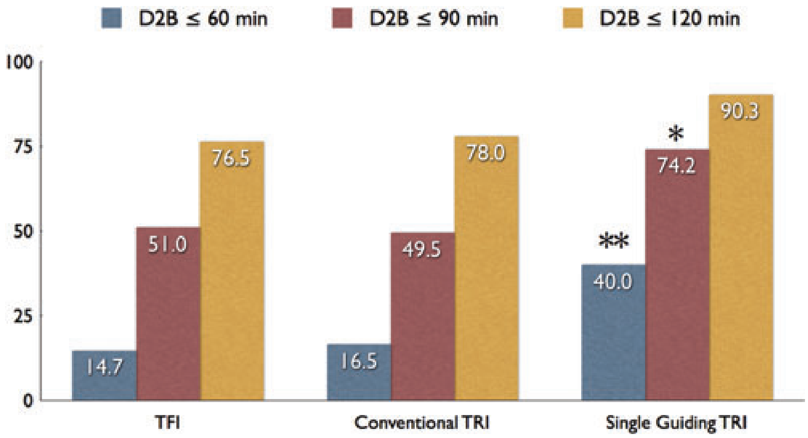

Figure 2. Proportions of patients achieving door-to-balloon (D2B) time within 60, 90, and 120 minutes according to intervention strategy. **, P = 0.008 versus transfemoral intervention (TFI) or conventional transradial intervention (Conventional TRI) group, *, P = 0.043 versus TFI or Conventional TRI group.

68.5 minutes, P = 0.008; Fig. 1). Proportions of patients achieving D2B time within 60 minutes and within 90 minutes increased significantly in the Single Guiding TRI group (within 60 minutes: 14.7% [TFI] and 16.5% [Conventional TRI] vs. 40.0%, P = 0.008; and within 90 minutes: 51.0% [TFI] and 49.5% [Conventional TRI] vs. 74.2%, P = 0.043; Fig. 2). Fluoroscopy time was also reduced in Single Guiding TRI group compared to Conventional TRI group (P = 0.004). Amount of contrast volume used did not differ among the 3 groups. Peak creatine phosphokinase (CPK) level and ejection fraction were similar among 3 groups.

Discussion

According to the most recent guideline,[1] patients with STEMI undergo aggressive anticoagulation (thrombolytics, glycoprotein IIb/IIIa inhibitors, aspirin, thienopyridines). Primary PCI should be associated with high access site bleeding complication in the case of TFI. Primary TRI reduces risk of periprocedural major bleeding and major adverse events with similar procedural success in the setting of acute STEMI.[9–11] This study also demonstrated that primary TRI could reduce all bleeding complications drastically (5.9% in TFI and 0% in TRI). However, in most studies, time required from puncture to reperfusion is similar in TFI and TRI groups. In one study, puncture-to-reperfusion time was 26 ± 13 and 25 ± 11 minutes in TRI and TFI groups, respectively,[10] whereas in a more recent study of elderly patients, it was 16.2 ± 4.5 and 15.4 ± 3.6 minutes in TRI and TFI groups, respectively.[11] In this study, we evaluated feasibility and efficacy of using a single catheter for both nonculprit and culprit vessel angiography and intervention. The main finding of this study is that use of a single guiding catheter during primary PCI is feasible and highly successful in most patients. As might have been expected, this simple technique saved time required for exchange of catheter(s), and reduced median N2B time from 13.8 (TFI) and 14.1 (Conventional TRI) to 7.6 minutes. Although reduction in N2B time might appear relatively modest, it translates into outcome differences. Because median D2B time was around 90 minutes, the proportion of patients achieving D2B time within 90 minutes increased significantly by small reduction in N2B time (from about a half to 74.2%). But, it should be emphasized that these findings are not applicable to the all catheterization lab. Any operator performing TRI faces a longer learning curve than for femoral approach. According to Louvard et al.,[12] transradial procedural failure rate will stabilize after 1,000 procedures at less than 1%, thus making the transradial procedure as successful as the transfemoral access. New operators should not attempt TRI in STEMI until they are quite comfortable with the technique.[13] Search for an ideal multipurpose catheter for both left and right coronary angiography is not new. Although several studies used an 8 or 7-Fr catheter in percutaneous femoral technique,[14,15] after introduction and widespread availability of preformed catheter with dedicated curve for left or right coronary artery, it has become routine procedure to use 2 diagnostic catheters for left and right coronary arteries selectively for TFI. During transradial angiography, using a single catheter for both left and right coronary angiography is an attractive idea, with potentially less procedure and fluoroscopy time, lower costs, diminished radial artery spasm, and relatively high success rates.[16–18] In our catheterization lab, we routinely use a single 4 Fr RM® 3.5 diagnostic catheter (Jungsung Medical) for left and right coronary angiography with a success rate of about 90% in more than 1,000 patients annually (unpublished data). During transradial primary PCI, using a single guiding catheter for both nonculprit and culprit vessel angiography and intervention has a potential to reduce N2B time. This study demonstrated that this simple technique reduced N2B and D2B times. Current ACC/AHA STEMI Guidelines[1] recommend that the D2B time be less than 90 minutes. N2B time is relatively short considering D2B time and total ischemic time. Numerous studies have attempted to reduce "system delay" or door-to-needle time in primary PCI patients by means of prehospital diagnosis,[2] prehospital activation of the catheterization laboratory and development of primary PCI protocol,[3] or new performance processes.[4] However, the goal of a D2B time less than 90 minutes remains to be achieved in all patients. In the United States, data on over 4,000 hospitals show that only 32% achieved a D2B time of less than 90 minutes,[19] and in Europe, first medical contact-balloon time for primary PCI varied between 60 and 117 minutes in 30 countries.[20] To achieve the goal of a D2B time within 90 minutes, it is helpful to reduce the N2B time as well as to reduce the "systemic delay." This study is the first study to date focusing on N2B time or "primary PCI procedure itself." In this study, N2B time was reduced about 6.2 minutes by using a single guiding catheter. But the difference in D2B time is about 21 minutes. As mentioned in the Methods section, this study enrolled all patients with acute STEMI between March 2009 and March 2011. Until October 2010, selection of vascular access route and diagnostic and guiding catheter was left to the discretion of the operator; however, since January 2011, a single guiding catheter was used as a default catheter during TRI. So patients in the Single Guiding TRI group were enrolled in the latest study periods. Starting in March 2010, we adopt 3 new performance processes to reduce the D2B time as a part of a Hospital Quality Improvement Project. (1) Short message service (SMS) after ECG check by the intern or the emergency physician working in the ED. SMS were sent concurrently to junior resident, senior resident, and cardiologist in charge on any ST segment change. (2) Concurrent activation of PCI team personnel at the ED by the resident doctor rather than the traditional stepwise activation.[4] Before the adoption of the new performance processes, the resident doctor called the cardiologist in charge when he interpreted the ECG as acute STEMI. The PCI team personnel were activated after the decision of the cardiologist in charge. But since March 2010, any resident doctor working in the ED has been empowered to activate the PCI team.[4] (3) We use TRI as a default route during primary PCI.[21] The only criterion on we used is a presence or absence of a palpable radial pulse. When a radial pulse was palpable, we performed primary PCI transradially. We did not prepare femoral access: No skin preparation including shaving of pubic hair, painting, or draping of femoral area was performed. In the catheterization lab, no femoral puncture needle, femoral sheath, or catheters were prepared. This strategy simplified the preparation of primary PCI, decreased nurse workload in ED and catheterization lab,[13] and reduced D2B time. Therefore, the reduction in D2B time is a reflection of evolution of primary PCI strategy in our hospital during the study period as well as using a single guiding catheter technique during primary transradial PCI. This study has several limitations: It was a single-center observational study without randomization, sample size was relatively small, and long-term clinical outcomes were not evaluated. However, this study included all STEMI patients treated during the study period, and it might be a reflection of real-world practice.

In conclusion, using a single guiding catheter during primary TRI for both nonculprit and culprit vessel angiography and intervention is feasible and highly successful, and might allow achievement of timely restoration of blood flow in infarct-related artery.

References

1. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation 2004;110:e82–e292.
2. Drew BJ, Sommargren CE, Schindler DM, et al. A simple strategy improves prehospital electrocardiogram utilization and hospital treatment for patients with acute coronary syndrome (from the ST SMART Study). Am J Cardiol 2011;107: 347–352.
3. Nishida K, Hirota SK, Seto TB, et al. Quality measure study: Progress in reducing the door-to-balloon time in patients with ST-segment elevation myocardial infarction. Hawaii Med J 2010;69:242–246.
4. Young HN, Kwang SC, Jeong HK, et al. Reduction of door-to-balloon time by new performance processes in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention. Angiology 2011;62: 257–264.

5. Ikari Y, Nakajima H, Iijima R, et al. Initial characterization of Ikari guide catheter for transradial coronary intervention. J Invasive Cardiol 2004;16:65–68.
6. Gwon HC, Doh JH, Choi JH, et al. A 5Fr catheter approach reduces patient discomfort during transradial coronary intervention compared with a 6Fr approach: A prospective randomized study. J Interv Cardiol 2006;19:141–147.
7. Youssef AA, Hsieh YK, Cheng CI, et al. A single transradial guiding catheter for right and left coronary angiography and intervention. EuroIntervention 2008;3:475–481.
8. R development Core Team. 2010. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3–900051-07–0. Available from: http://www.R-project.org/. Accessed Mar 1, 2011.
9. Valsecchi O, Musumeci G, Vassileva A, et al. Safety, feasibility and efficacy of transradial primary angioplasty in patients with acute myocardial infarction. Ital Heart J 2003;4:329–334.
10. Kim JY, Yoon J, Jung HS, et al. Feasibility of the radial artery as a vascular access route in performing primary percutaneous coronary intervention. Yonsei Med J 2005;46:503–510.
11. Yan ZX, Zhou YJ, Zhao YX, et al. Safety and feasibility of transradial approach for primary percutaneous coronary intervention in elderly patients with acute myocardial infarction. Chin Med J (Engl) 2008;121:782–786.
12. Louvard Y, Krol M, Pezzano M, et al. Feasibility of routine transradial coronary angiography: A single operator's experience. J Invasive Cardiol 1999;11:543–548.
13. Amoroso G, Laarman GJ, Kiemeneij F. Overview of the transradial approach in percutaneous coronary intervention. J Cardiovasc Med (Hagerstown) 2007;8:230–237.
14. Schoonmaker FW, King SBr. Coronary arteriography by the single catheter percutaneous femoral technique. Experience in 6,800 cases. Circulation 1974;50:735–740.
15. el-Gamal M, Slegers L, Bonnier H, et al. Selective coronary arteriography with a preformed single catheter: Percutaneous femoral technique. Am J Roentgenol 1980;135: 630–632.
16. Sanmartin M, Esparza J, Moxica J, et al. Safety and efficacy of a multipurpose coronary angiography strategy using the transradial technique. J Invasive Cardiol 2005;17: 594–597.
17. Kim SM, Kim DK, Kim DI, et al. Novel diagnostic catheter specifically designed for both coronary arteries via the right transradial approach. A prospective, randomized trial of Tiger II vs. Judkins catheters. Int J Cardiovasc Imaging 2006;22:295–303.
18. Fang Y, Yang C, Wang X, et al. Feasibility and application of single 5F multipurpose catheter in coronary and peripheral angiography via a transradial approach. Int J Cardiol 2011;151:182–186.
19. Vasaiwala S, Vidovich MI. Door-to-balloon and door-to-needle time for ST-segment elevation myocardial infarction in the U.S. J Am Coll Cardiol 2009;53:902; author reply 902–903.
20. Widimsky P, Wijns W, Fajadet J, et al. Reperfusion therapy for ST elevation acute myocardial infarction in Europe: Description of the current situation in 30 countries. Eur Heart J 2010;31:943–957.
21. Kim JY, Yoon J. Transradial approach as a default route in coronary artery interventions. Korean Circ J 2011;41: 1–8.