

Safety of One-Day Admission Transradial Coronary Intervention

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ABSTRACT

Background : Recent advances of percutaneous coronary intervention (PCI) and transradial coronary intervention (TRI) have made it possible to reduce the local complication rate and the time until a return to ambulation. The aim of this study is to assess the safety and the patient satisfaction of the TRI-based one-day admission program for PCI. **Methods :** Total 230 consecutive patients underwent TRI on the day of admission, according to pre-determined inclusion criteria, from May 2001 to October 2003. The subjects were examined for clinical and angiographic characteristics. The patients having a same-day discharge were telephone-interviewed one day and seven days after discharge to assess late complications and the patients' satisfaction. **Results :** The mean age of the subjects was 59 ± 9 years and 77.4% were male patients. 169 (73.4%) had stable angina and 37 (16.1%) had unstable angina. Stents were implanted in 178 cases (69.3%). Of the 230 patients who underwent TRI, 206 patients (89.6%) could discharge on the same day after the procedure. The procedure was successful in 98.5%. The average hospital stay for them was 9.4 ± 1.4 hours. Two subjects reported hematoma near the puncture site within 24 hours after discharge, and one reported this problem 7 days after discharge. During the follow-up, there were no cases reporting chest pain needing rehospitalization or such complications as subacute vessel closure. No deaths, myocardial infarctions or revascularization were noted during the follow-up period. The majority of the patients ($n=197$, 95.6%) were satisfied with the same-day admission and discharge. **Conclusions :** Same-day admission and discharge after TRI seems to be safe as well as satisfactory for not low-risk patients. (Korean Circulation J 2004; 34(7):647-654)

KEY WORDS : Coronary disease ; Angioplasty ; Radial artery.

Introduction

Because of its invasiveness and risk of potential complications, diagnostic coronary angiography or percutaneous coronary intervention (PCI) are commonly performed as inpatient procedures. However, with improved equipment technology and the accumulation of

experiences, diagnostic coronary angiography is increasingly performed on an outpatient basis in many cardiovascular centers.¹⁾ However, PCI has still been performed as an inpatient procedure, with the average lengths of stay ranging from 2–3 days in the majority of cases. The two major reasons for keeping the patient under clinical observation is the risk of subacute closure of the target vessel after discharge and immobilization to reduce the risk of puncture site-related bleeding complications if the procedure was performed via a transfemoral approach.

Recent advances in equipment technology, such as the advent of coronary stent and enhanced clinical expertise, have reduced the acute complications after the

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procedure.²⁾ Also, the development of a procedure via a transradial approach³⁾ and vascular closure devices that achieve early ambulation have contributed to the decreased length of hospital stay. In recent studies in other countries, the feasibility of same-day discharge has been demonstrated, not only after transradial PCI,⁴⁻⁶⁾ but also after transfemoral PCI.⁷⁻⁹⁾ Such trends are accelerating due to the introduction of vascular closure devices.¹⁰⁻¹²⁾ Particularly, transradial coronary intervention (TRI) is considered as the most suitable for a same-day discharge procedure because of the advantages that compression hemostasis can be performed easily, puncture site complications rarely occur and its indication widens with the accumulation of operator experience of performing TRI. However, a same-day discharge PCI remains to be reported in Korea. Thus, the feasibility of a same-day discharge and its safety on patients undergoing transradial coronary intervention (TRI) on an outpatient basis were prospectively investigated.

Methods

Patient selection

The study population was comprised of all patients diagnosed with coronary artery disease that had undergone transradial coronary intervention on the day of admission, under the same-day admission and discharge program, between May 2001 and October 2003, at the cardiac and vascular center of Samsung Medical Center. Although the following patients are included in the study, they were not discharged on the same day: cardiogenic shocks during or after the procedure, systemic or distal embolization, severe complications related to the procedure, such as cardiac arrest, left main PCI, medical history of myocardial infarction within one week, presence of intracoronary thrombus or severe coronary artery dissection, left ventricular ejection fraction lower than 30% and a serum creatinine greater than 2.0 mg/dL.

Periprocedural medication

All patients were treated with 100–300 mg aspirin and

75 mg clopidogrel daily for 3–5 days prior to the procedure. Before or immediately after the procedure, a loading dose of 300 mg clopidogrel was administered to patients not previously treated with clopidogrel on the several days prior to the procedure. Patients without contraindications were maintained on clopidogrel 75 mg/day for one month and aspirin indefinitely. Immediately prior to the procedure, the administration of heparin was adjusted to 100 U/Kg and the activated clotting time (ACT) maintained between 300 and 350 seconds.

Procedural protocol

TRI was performed with the use of 5–7 French guiding catheters through the right or left radial artery. Immediately after the procedure, the arterial sheath was removed in the catheterization laboratory and a pressure dressing applied at the radial puncture site. After 4 hours, the pressure dressing was removed and the presence or absence of a radial artery pulse, bleeding and hematomas were assessed. If the patient was in a stable condition, without chest pain and electrocardiographic change during a postprocedural observation period, they were discharged 2 hours later on the same day.

Study method

The clinical, angiographic and procedural characteristics, and the procedural success rate were assessed on the study patients. Lesions were characterized according to the American College of Cardiology/American Heart Association (ACC/AHA) classification system. Successful PCI was defined as a residual diameter stenosis <30% after balloon angioplasty or stent implantation, with TIMI 3 flow and the patient in a stable condition, and without acute myocardial infarction, the need for emergency coronary artery bypass graft surgery (CABG) or death.

To assess late complications and patient satisfaction, structured follow-up telephone interviews were performed 24 hours and 7 days after discharge. The occurrence of chest pain, a puncture site complication (pain, bleeding and hematoma) and readmission status were evaluated.

In addition, the satisfaction of same-day discharge and the preference between same-day discharge and treatment as an inpatient were assessed.

Statistical analysis

All data are presented as the mean \pm SD. Statistical analysis was performed by Student's t- or Chi-squared tests using SPSS for 11.0. $p < 0.05$ was considered as statistically significant.

Results

Clinical characteristic

During the study period, a total 230 patients (257 lesions) underwent transradial coronary intervention (TRI) on the day of admission. There were 178 male and 52 female cases (77.4 and 22.6%, respectively), with a mean age of 59 ± 9 years. The clinical diagnoses of the study population were stable angina, which was most prevalent, unstable angina, silent ischemia, and mixed angina

in 169 (73.4%), 37 (16.1%), 19 (8.3%) and 5 (2.2%) cases, respectively. 43 (18.7%), 80 (34.8%) and 6 (2.6%) cases had prior myocardial infarction, PCI and CABG, respectively. The left ventricular ejection fraction, as evaluated by echocardiogram, was $59 \pm 9\%$ (Table 1).

Angiographic characteristic

With regard to the number of diseased vessel, there were 146 (63.5%), 49 (21.3%) and 39 (17.0%) cases of a single vessel disease, two vessel disease and three vessel disease, respectively. The vessels that underwent TRI ($n=257$) were as follows: the left anterior descending artery, the right coronary artery, the left circumflex artery and the bypass graft vessel in 112 (43.6%), 94 (36.6%), 50 (19.4%) and 1 (0.4%) cases, respectively. The lesion type according to the ACC/AHA classification was as follows: Types A, B1, B2 and C lesions in 65 (25.3%), 75 (29.2%), 53 (20.6%) and 64 (24.9%) cases, respectively (Table 2).

Table 1. Clinical characteristics

Clinical parameter	All cases	Same day discharge	Next day discharge	p
Number	230	206 (89.6%)	24 (10.4%)	NS
Age (years)	59 ± 9	59 ± 9	59 ± 7	NS
Male sex	178 (77.4%)	163 (79.1%)	15 (62.5%)	NS
Hypertension	113 (49.1%)	102 (49.5%)	11 (45.8%)	NS
Diabetes mellitus	54 (23.5%)	46 (22.3%)	8 (33.3%)	NS
CVA history	10 (4.3%)	9 (4.4%)	1 (4.2%)	NS
Hypercholesterolemia	42 (18.3%)	39 (18.9%)	3 (12.5%)	NS
Family history	10 (4.3%)	9 (4.4%)	1 (4.2%)	NS
Smoking	66 (28.7%)	60 (29.1%)	6 (25.0%)	NS
Previous MI	43 (18.7%)	40 (19.4%)	3 (12.5%)	NS
Previous PCI	80 (34.8%)	80 (38.8%)	0 (0.0%)	0.001
Previous CABG	6 (2.6%)	5 (2.4%)	1 (4.2%)	NS
Ejection fraction (%)	59 ± 9	60 ± 11	57 ± 8	NS
Clinical diagnosis				
Stable angina	169 (73.4%)	152 (73.8%)	17 (70.8%)	NS
Unstable angina	37 (16.1%)	33 (16.0%)	4 (16.7%)	NS
Silent ischemia	19 (8.3%)	17 (8.3%)	2 (8.3%)	NS
Mixed angina	5 (2.2%)	4 (1.9%)	1 (4.2%)	NS

Values are presented as numbers (relative percentages) or mean \pm SD. CVA: cerebrovascular accident, MI: myocardial infarction, PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft

Procedural characteristic

The TRI was performed on 257 lesions in 230 patients. A multivessel procedure was performed in 24 cases (10.4%). As the lesion treatment, stent implantation was performed in 178 cases (69.3%), with 190 stents used. In 55 cases (21.4%), only balloon angioplasty was performed. Angioplasty using a cutting balloon was performed on 24 cases (9.3%). The guiding catheters used in TRI were as follows : 6 French, which was most common, 5 French and 7 French in 118 (51.3%), 101 (43.9%) and 11 (4.8%), respectively (Table 3).

Same day discharge

Of the 230 patients that underwent TRI on the day of admission, 24 (10.4%) were unable to be discharged on the same day. The reasons for failure of same-day discharge were that clinicians or patients did not want to be discharged for the reason unrelated to the result of procedure, complications related to the procedure, a high risk procedure, such as a bifurcation lesion, the development of new thrombus after stent deployment and the development of ventricular tachycardia requiring electrical cardioversion during procedure, in 9, 9, 3, 2 and 1 cases, respectively.

Of the 206 patients successfully discharged on the same day, the intervention failed in 3 cases (1.5%), 2 due to the failure of guidewire passage in the completely occluded artery and 1 that showed 75% residual stenosis after the balloon angioplasty for a completely occluded artery. In 12 cases (5.8%), complications related to the procedure occurred. Of these, there was 10 (4.9%) cases of coronary artery dissection and 1 case each of side branch occlusion and dissection of the sinus valsalva, respectively (Table 3).

Of the 24 patients who were unable to be discharged on the same day, only 1 case (4.2%) was due to failure of the procedure because of type B dissection and 50% residual stenosis after balloon angioplasty for the ostial lesion on the diagonal branch of the left anterior descending artery. In 9 cases (37.5%), complications related to the procedure occurred; coronary artery dissection, side branch occlusion and left anterior descending artery perforation in 5 (20.8%), 3 (12.5%) and 1 (4.2%) cases, respectively (Table 3).

The mean hospital stay and average discharge time of the same-day discharge patients were 9.4 ± 1.4 hours and 17.1 ± 1.3 o'clock, respectively.

Table 2. Angiographic characteristics

Clinical parameter	All cases	Same day discharge	Next day discharge	p
Number	230	206	24	
Diseased extent				
1 vessel	146 (63.5%)	137 (66.5%)	9 (37.5%)	0.005
2 vessel	49 (21.3%)	38 (16.5%)	11 (45.8%)	0.003
3 vessel	39 (17.0%)	35 (17.0%)	4 (16.7%)	NS
Treated vessels (N)	257	226	31	
LAD	112 (43.6%)	96 (42.5%)	16 (51.6%)	NS
RCA	94 (36.6%)	85 (37.6%)	9 (29.0%)	NS
LCX	50 (19.4%)	44 (19.5%)	6 (19.4%)	NS
Bypass graft	1 (0.4%)	1 (0.4%)	0 (0.0%)	NS
Lesion type (N)	257	226	31	
A	65 (25.3%)	61 (27.0%)	4 (12.9%)	NS
B1	75 (29.2%)	68 (30.1%)	7 (22.6%)	NS
B2	53 (20.6%)	42 (18.6%)	11 (35.5%)	NS
C	64 (24.9%)	55 (24.3%)	9 (29.0%)	NS

LAD: left anterior descending artery, RCA: right coronary artery, LCX: left circumflex artery

Table 3. Procedural characteristics

	All cases	Same day discharge	Next day discharge	p
Case number	230	206	24	
Multivessel procedure	24 (10.4%)	17 (8.3%)	7 (29.2%)	NS
Procedural success rate	226 (98.3%)	203 (98.5%)	23 (95.8%)	NS
Procedural complication	21 (9.1%)	12 (5.8%)	9 (37.5%)	0.0001
Used guiding catheter				
5 French	101 (43.9%)	92 (44.7%)	9 (37.5%)	NS
6 French	118 (51.3%)	107 (51.9%)	11 (45.8%)	NS
7 French	11 (4.8%)	7 (3.4%)	4 (16.7%)	0.004
Lesion number	257	226	31	
Stent implantation	178 (69.3%)	155 (68.6%)	23 (74.2%)	NS
Balloon dilatation	55 (21.4%)	48 (21.2%)	7 (22.6%)	NS
Cutting balloon	24 (9.3%)	23 (10.2%)	1 (3.2%)	NS
Type A dissection	8 (3.1%)	7 (3.1%)	1 (3.2%)	0.005
Type B dissection	7 (2.7%)	3 (1.3%)	4 (12.9%)	0.002
Side branch occlusion	4 (1.6%)	1 (0.4%)	3 (9.7%)	0.006

Follow-up

Within 24 hours of the same-day discharge, a hematoma at the puncture site occurred in 2 cases (1.0%) between 24 hours and 7 days in 1 (0.5%). The bleeding at the puncture site within 24 hours after discharge occurred in 2 cases (1.0%). The amount of bleeding was small, equivalent to a sheet of gauze, and did not require additional treatment. The development of chest pain within 24 hours and between 1 and 7 days of discharge occurred in 11 (5.3%) and 23 (11.2%) cases, respectively. However, no severe chest pain requiring repeat coronary angiography or readmission developed. During the follow-up period, complications such as subacute thrombosis and major cardiac events, such as myocardial infarction, requiring repeat PCI or CABG, did not occur, and there were no deaths (Table 4).

In the survey for the patients' satisfaction of same-day discharge, 197 of 206 cases (95.6%) were satisfied and preferred same-day discharge to treatment as an inpatient. Of the 9 dissatisfied cases, the were 3 males and 6 females, with a mean age of 58 ± 7 years. Their reason for dissatisfaction was psychological anxiety (Table 4).

Table 4. Local wound complications and patient satisfaction after same-day discharge

	After 24 hour	After 7 days
Puncture site complication		
Pain	36 (17.5%)	15 (7.3%)
Hematoma	2 (1.0%)	1 (0.5%)
Bleeding	2 (1.0%)	0
Death	0	0
Myocardial infarction	0	0
Repeat PCI or CABG	0	0
Readmission	0	0
Satisfied with same-day discharge	197 (95.6%)	197 (95.6%)

PCI: percutaneous coronary intervention, CABG: coronary artery bypass graft

Discussion

With the expanding indication for PCI in the treatment of symptomatic coronary artery diseases the proportion of its use is gradually increasing, and PCI has generally been performed as an inpatient procedure. One of major reasons for performing PCI as an inpatient procedure is the risk of occlusion of the target vessel after discharge. Prior to the general use of stents, depen-

ding on the number of related risk factors present with a vessel occlusion, the incidence of acute vessel closure has been reported to be 2–25%.¹³⁻¹⁷⁾ The major cause has been reported as coronary artery dissection, which frequently occurs within minutes or a few hours after the procedure.¹⁶⁾ However, stenting, although initially introduced as a treatment for acute vessel closure, is now widely practiced electively, making acute vessel closure a rare complication. Now, a subacute stent thrombosis is the more prevalent postprocedural thrombotic complication. The predictors of the risk of stent thrombosis include multiple stents, smaller vessel, pre-intervention thrombosis, suboptimal stent expansion, residual dissection and slow flow, etc., which are mainly related with suboptimal PCI result.¹⁸⁾¹⁹⁾ If an optimal result after stenting is achieved, the risk may be decreased. In addition, the administration of new anti-platelet agents, such as ticlopidine or clopidogrel, has been reported to reduce the incidence of subacute thrombosis to less than 2%.²⁰⁾

Ziakas, et al.⁶⁾ reported in a retrospective study of same-day discharge on 943 patients, that subacute vessel closure occurred in only 0.6% of patients, but it did not occur during the first 24 hours after discharge, and reported same-day discharge as safe and feasible in certain patients with low-risk for postdischarge complications. Similarly, in our study, the development of subacute thrombosis within 7 days of the same-day discharge was not detected. Thus, in the same-day discharge patients, the risk due to subacute vessel occlusion after the procedure would not be increased if the angiographic result after the procedure was optimal and the condition of the patient stable.

Another important reason for hospitalization is that the procedure requires prolonged immobilization to reduce the risk of puncture site-related bleeding complications, particularly in the cases of a transfemoral approach. The reported incidence of puncture site complications after the procedure varies from 1.5 to 18%, which has been reported to be associated with the level of anticoagulation, the sheath size and sheath dwell time.²¹⁾ However, the advantages of the transradial approach

is that the distal radial artery has a superficial course, lies isolated from major veins or nerves and is easy to compress; thus, bleeding complications are extremely rare, and even if occlusion of the radial artery occurs after the cannulation procedure, the functional impairment due to the ischemia in hand is extremely rare due to the presence of the collateral blood supply from the ulnar artery. A recent randomized comparison study has shown that major entry site complications were encountered in 2.0% of cases in a transfemoral group, but in none of the transradial group, and the procedural and clinical outcomes of PCI were similar for both groups.²²⁾ Hence, with transradial coronary intervention (TRI), the advantages are that same-day discharge is feasible as major vascular complications are rare and the restriction of activity is limited; consequently, the procedure allows busy contemporary individuals to return to work earlier and shortens the hospital stay, resulting in reduced medical costs.

Kiemeneij, et al.⁴⁾ reported the safety of same-day discharge on 100 patients who underwent the Palmaz-Schatz stent implantation through the transradial approach between 1994 and 1995. Although, the results are currently difficult to apply, as a proportion of the patients were receiving anticoagulation with Coumadin, the study suggested the potential of PCI on an outpatient basis without complications. Subsequently, Slagboom, et al.⁵⁾ compared the outcome of 159 patients who underwent the transradial PCI using 6 French guiding catheters, and divided the patients into two groups, the same-day discharge group and the 24-hour clinical group, based on a set of clinical and angiographic parameters, and predictive indicators of adverse clinical events during the first 24 hour. The data demonstrated that 106 patients (66%) were considered suitable for same-day discharge without cardiac and vascular complications, which has shown very encouraging results in terms of the safety of same-day discharge. In this study, 56% of treated lesions were type A, and stents were used in only 40% of patients, with none undergoing a multivessel procedure. However, our study included relatively high

risk patients with unstable angina (n=33, 16.0%) and types B2 and C lesions (n=97, 42.9%), and patients that underwent a multivessel procedure (n=17, 8.3%), with 68.6% of patients underwent stent implantation. Therefore, the significance of our results is in the demonstration of the potential for successful same-day discharge on a larger number and variety of patients, without increased risk of major cardiac events or puncture site complications.

On the other hand, in other countries same-day discharge has been reported to be safe, not only in the procedure via transradial approach, but also in the procedure via transfemoral approach, and the degree of patient satisfaction is high,⁶⁾⁽⁹⁾⁽²³⁾ with the additional advantage of cost reduction.¹⁰⁾⁽²³⁾ In our study, 95.6% of patients preferred the same-day discharge procedure, which indicates the high patient satisfaction rate. Under current conditions, with the prevalence for coronary stents, high-pressure stent deployment²⁴⁾ and the development of powerful anti-platelet agents,²⁵⁾⁽²⁶⁾ the incidence of sub-acute thrombosis is rare, less than 1%. Even in high risk patients, same-day discharge can be carried out safely if an optimal final result after PCI is achieved. Particularly in the transradial PCI, as puncture site complications are extremely rare and early ambulation is feasible, same-day discharge is expected to raise the satisfaction of patients and reduce medical costs.

This study is a prospective registry on the outcome of patients that underwent TRI on the day of admission under the planned same day admission and discharge program. Therefore, clinical or angiographic parameters for predicting same-day discharge could not be accurately defined. However, in those treated as inpatients, significantly more multivessel diseases were detected and a significantly larger guiding catheter used. Hence, for the accurate assessment of the safety and patient selection for same-day discharge, larger scaled randomized multi-center trials are required to compare with the inpatient population. In addition, as the large majority of domestic cardiovascular centers perform the procedure via the transfemoral approach, further study is required to

assess the outcome of same-day discharge after transfemoral PCI.

In conclusion, it is considered that for patients with a stable condition and minimal complications after the procedure, the same-day admission and discharge TRI reduces the hospital stay, possibly increases patient satisfaction and may prevail in the field of interventional cardiology in Korea.

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