The Efficacy and Safety of Transradial Approach in Comparison with Transfemoral Approach for Coronary Angiography and ad hoc Coronary Angioplasty in Thailand

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***Objective**: To assess the efficacy and safety of transradial approach compared with transfemoral approach for coronary angiography and ad hoc angioplasty in Phramongkutklao hospital at the time of initiation of transradial program.*
***Material and Method**: Prospective data collection of consecutive patients who underwent coronary angiography with ad hoc angioplasty during October 2004 to January 2005 was conducted. Baseline demographic data and the details of the procedure were recorded. The complications were assessed by a single doctor using standard protocol.*
***Results**: There were 75 included in our study. Transradial approach and transfemoral approach was performed in 23 cases (30.7%) and 52 cases (69.3%), respectively. The baseline characteristics, procedure results were similar, except the there was higher prevalence of NST-ACS symptoms (92.31% vs. 65.22%, p = 0.004) and access site complications in transfemoral group (23.08% vs. 4.35%, p = 0.035). The success rate was very high (> 90%) and not significantly different in both groups. However, the transradial group was associated with lower assess site complications earlier ambulation and better patient's satisfaction.*
***Conclusion**: Even at the time of initiation of transradial program, transradial approach for coronary angiography and ad hoc angioplasty can be performed with similar efficacy, less local complication, earlier ambulation and better patient's satisfaction compared to the standard transfemoral approach.*

***Keywords**: Transradial approach, Coronary angiography, Ad hoc angioplasty, Efficacy and safety*

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Coronary angiography and coronary angioplasty are the standard procedure for diagnosis and treatment of coronary artery disease[1-3]. At present, most coronary angiography and coronary angioplasty are performed via femoral artery using Seldinger's technique. Transradial approach, since first introduced to clinical practice in 1989[4], has become a good alternative to the conventional transfemoral approach for performing coronary angiography and coronary angioplasty. Previous studies have shown excellent success rates and very low complication rates of transradial approach[5-10]. However, most data are from the dedicated, high volume centers that have performed many cases of transradial coronary angiography and angioplasty. The results of transradial approach in the centers that just started to perform transradial procedure are very limited. This study aims to compare the efficacy and safety of transradial versus transfemoral approach for coronary angiography and ad hoc coronary angioplasty in a centre that just adopted the transradial program.

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Material and Method

This study is a prospective cohort study. All

consecutive patients who received coronary angiography and ad hoc coronary angioplasty at Phramongkutklao Army hospital during October 2004 to January 2005 were recruited into this study. The exclusion criteria included acute ST-elevation myocardial infarction, previous bypass surgery, cardiogenic shock, negative Allen's test, and procedures that require special equipments that need guiding catheter larger than 6 French in diameter (*e.g.* rotablator). All patients gave written informed consent. The baseline characteristics were collected. The patients received coronary angiography and ad hoc angioplasty according to the current standard guideline at that time. The choice of approach, either transfemoral or transradial, was made by the patients' interventional cardiologists. In-hospital events were followed by independent physician who was not involved in the procedure.

All transradial procedures were performed via right radial arteries with 6 French sheaths. Unfractionated heparin was given to keep activated clotting time (ACT) between 250-300 seconds in both groups. The sheaths were removed 4 hours after the procedure in transfemoral group and were removed immediately after the procedure in transradial group. The duration before starting ambulation for each patient was decided by the interventional cardiology who performed procedures. The patients were followed-up 24 hours after procedures. The complications were recorded and the patients' satisfaction was evaluated using questionnaires. The definition of procedure success in coronary angiography was the ability to selectively engage and adequately visualize all the coronary trees. The definition of procedure success in coronary angioplasty was the ability to perform angioplasty with residual stenosis less than 30%. The serious bleeding complications included bleeding that required blood transfusion, bleeding complications that required surgical correction or fatal bleeding. The hematoma larger than 2.5 centimeters in diameter was defined as significant.

Statistical analysis

Demographics and clinical characteristics between transradial and transfemoral groups were expressed as mean $\pm$ SD for continuous variables with normal distribution; on the other hand, median, minimum, and maximum was presented or as a percentage of the group of origin for categorical variables. Comparative analysis of categorical variable was performed using a Chi-square test or Fisher's exact test. Continuous variables were analyzed using Independent t tests for normally distribution; otherwise, the Mann-Whitney U test was employed. All p-value are two-tailed, and p-value ≤ 0.05 was considerate to indicate statistical significance. All statistical analysis in this study was performed using SPSS software (version 13.0, SPSS Inc, Chicago).

Results

There were 242 cases undergoing coronary angiography during that four-month period. Of 242 patients, 167 cases underwent coronary angiography alone and did not proceed to angioplasty. Seventy five cases underwent coronary angiography and ad hoc angioplasty and were included in our study. Transradial approach and transfemoral approach was performed in 23 cases (30.7%) and 52 cases (69.3%), respectively. The baseline characteristics of the patients were shown in Table 1. All demographic data were comparable in both groups except for a trend for higher ratio of male in transradial approach (86.96% vs. 65.38%, $p = 0.055$).

The indications for coronary angiography and ad hoc angioplasty were shown in Table 2. The ratio of patients with unstable angina or non-ST elevation myocardial infarction (NSTEMI) was higher in transfemoral approach whereas in transradial approach the ratio of patients with positive exercise test was higher.

The details of the procedure results were shown in Table 3. The procedure time, fluoroscopic time, number of cines taken and amount of contrast media used were comparable in both groups. The number of lesions received angioplasty was not statistically significant in transradial and transfemoral groups (1.1 vs. 1.28, $p > 0.05$). The procedural success was slightly lower in transradial group but the difference was not statistically significant (91.3% vs. 96.15%, $p = 0.582$). In patients who received transradial approach, 2 cases failed due to abnormal anatomy of the arm vessels and lack of adequate guiding support. The patients had to switch to transfemoral approach. Two cases in transfemoral approach failed due to tortuousity of iliac artery and aorta and the patient had to switch to transradial approach.

The actual time from the end of procedure to the time that individual patient started to ambulate (sitting and walking) was recorded. The median duration that the patients had to lie flat before they could sit up and started to walk was 6 hours and 12 hours, respectively in transfemoral group, which was much longer than transradial group. All transradial patients

Table 1. Demographic and Clinical Characteristics

Characteristics	Transradial (n = 23)	Transfemoral (n = 52)	p-value
Age (yr)	67.22 ± 10.33	63.40 ± 10.62	0.152
Sex-no. (%)			
Male	20 (86.96)	34 (65.38)	0.055
Body mass index*	24.86 ± 2.98	24.40 ± 3.47	0.583
History of CAD[1]-no. (%)	8 (34.78)	15 (28.85)	0.607
Diabetes-no. (%)	10 (43.48)	18 (34.62)	0.464
Hypertension-no. (%)	16 (69.57)	36 (69.23)	0.977
Dyslipidemia-no. (%)	10 (43.48)	28 (53.85)	0.408
Current smoking-no. (%)	1 (4.35)	3 (5.77)	1.000*
Creatinine (μmol/liter)[2]	101.61 ± 35.50	107.58 ± 56.76	0.800[3]
Previous stroke	1 (4.35)	1 (1.92)	0.522*
Peripheral vascular disease	0 (0.00)	0 (0.00)	N/A

* Presented by Mean ± SD, ** Body mass index = weight/height2 (body weight in kg, height in M)
[1]CAD: coronary artery disease
[2]To convert values to milligrams per deciliter, divide by 88.4
[#] Fisher's Exact Test, [3]Mann-Whitney U Test

Table 2. Indications for Coronary Angiography with Intervention

Indications	Transradial (n = 23)	Transfemoral (n = 52)	p-value[#]
NSTEMI* or unstable angina	15 (65.22)	48 (92.31)	0.006
Positive exercise stress test	6 (26.08)	1 (1.92)	0.003
Others	2 (8.69)	3 (5.77)	0.639

* NSTEMI: Non-ST segment elevated myocardial infarction, [#] Fisher's Exact Test

Table 3. Procedure details and results-Median (Min-Max)

Variables	Transradial (n = 23)	Transfemoral (n = 52)	p-value**
Proceduretime (min)	46 (18-76)	40 (4-99)	0.223
Fluoroscopic time (min)	10.9 (5.0-22.1)	12.4 (2.4-252.0)	0.535
Amount of pictures	17 (10-29)	17 (8-42)	0.954
Contrast volume (ml)	100 (30-160)	120 (40-320)	0.068
Successful procedures-n (%)	21 (91.30)	50 (96.15)	0.582[#]
Duration before ambulation (sitting)*	0 (0-0)	6 (6-8)	< 0.001
Duration before ambulation(walking)*	0 (0-0)	12 (12-18)	< 0.001

*Duration before ambulation (hour), **Mann-Whitney U Test, [#] Fisher's Exact Test

started to ambulate immediately after the procedure. In fact, many patients walked out from the cardiac catheterization laboratory to the adjacent recovery area by themselves under the supervision and support from our nursing staffs.

The access site complication was much lower in transradial group compared with transfemoral group (4.35% vs. 23.08%, p = 0.035). There was no serious complication in both groups. In terms of pain from the procedure, the two approaches were not different.

Table 4. Complications*

Variable	Transradial (n = 23)	Transfemoral (n = 53)	p-value
Access site complication-no. (%)	1 (4.35)	12 (23.08)	0.035 #
Bruise and hematoma	0 (0.00)	11 (21.15)	0.015 #
Bleeding	1 (4.35)	1 (1.92)	0.522 #
Required blood transfusion	0 (0.00)	0 (0.00)	N/A
Urgent surgery	0 (0.00)	0 (0.00)	N/A
Pain severity			0.313 #
1. no pain	16 (69.57)	33 (63.46)	
2. minimal pain	6 (26.09)	17 (32.70)	
3. pain required medication	0 (0.00)	2 (3.85)	
4. pain not relieved by medication	1 (4.35)	0 (0.00)	
Embolic complication	0	0	N/A

* One patient may have more than one complications, # Fisher's Exact Test

There was no embolic or thrombotic complication in both groups. The patients who received transradial approach could ambulate much earlier and the patient satisfaction, evaluated by questionnaire, was much better with transradial approach.

Discussion

To our knowledge this is the first prospective observational study comparing the safety and efficacy of transradial approach and transfemoral approach in Thailand. The results reflected the outcomes of transradial approach in a cardiac catheterization laboratory that just started the transradial program. Before that period, transradial approach had been performed in only few selected cases in our institute. During the study period, transradial approach was adopted by the interventional cardiologists in our hospital and the ratio of transradial approach to transfemoral approach at that time was approximately 1:2.

The baseline characteristics of both groups were similar except the ratio of male to female in transradial group was, although not statistically significant, higher than transfemoral group. This may be due to the smaller size of radial artery and more negative Allen's test in female. Previous study revealed that the radial artery size in Asian population was smaller than in Western population and the vessel size in female was smaller than in male[11].

The results from our study were comparable to many previous studies from the high volume centers that dedicatedly performed transradial intervention[5-10,12-14]. The success rate in transradial group was very high and similar to the results from other studies.

The ratio of unstable angina or NSTEMI was higher in transfemoral group. This is due to the fact that during the initiation of transradial program, many interventional cardiologists still selected transfemoral approach for potentially more complicated cases due to the belief that transradial approach consumed more time and may required more contrast because of technical difficulty. In our study, the time of procedure, fluoroscopy time and amount of contrast used were similar in both groups. This confirms that transradial approach was feasible and effective. Although, transradial approach may be technically more difficult and need some learning curve[15,16], especially for those interventional cardiologists who were familiar with the traditional transfemoral technique and had just begun to performed transradial approach, our data showed that adopting transradial approach was a very good strategy.

The rate of complications of transradial approach in our study was very low and was comparable to other previous studies[5-10,12-14]. Transfemoral approach was associated with higher incidence of bruising and hematoma compared with transradial approach.

Taking into consideration the fact that transradial approach had similar procedure time, success rate and much lower bleeding complication, our study support the concept of using this approach for patient with acute coronary syndrome who usually are treated with multiple anti-platelets and anti-coagulations. There have been many trials reported the success of using transradial approach in acute myocardial infarction[17-22]. Another situation that transradial might be very useful is the patients with

failed thrombolytics (rescue angioplasty) who have very high rate of access site and bleeding complications. There were few limitations in our study. First, it was not a randomized study. There might be possible bias in terms of patients' selection and outcome measurement. The transfemoral group had more patients with UA/NSTEMI and might have higher risk than the patients in transradial group. Second, we did not use the ACC/AHA classification to identify the severity of the angioplasty lesions. However, the number of cine, the procedural time and the fluoroscopy time were used to reflect the complexity of the lesions. Since both approach had the same amount of fluoroscopy time, number of cine taken, and procedural time, we assumed that the complexity and difficulty of the lesions in both group were similar. Third, the number of cases was relatively small. After excluding STEMI, patients who required special procedures, post-CABG patients, patients who were admitted for staged angioplasty and patients who did not sign informed consent, there was total of 242 cases undergoing coronary angiography during that 4-month period of our study. Of those 242 cases, only 75 cases proceeded to ad hoc angioplasty. The number is quite small and not justified for subgroup analysis.

The strength of our study lies on including all incomers who presented to our catheterization laboratory. The results represented the real world outcomes of practice in a moderate size catheterization laboratory at the beginning of transradial program. Our study has great clinical applications. The result encourages more cardiac catheterization laboratories to consider transradial approach as an alternative for the traditional transfemoral approach. The result of our study serves to fill the knowledge gap of the current evidence derived mainly from the high volume, highly experienced center. Even at the time of beginning of the transradial approach, the outcome of transradial approach was very promising.

Conclusion

Even at the time of initiation of transradial program, transradial approach for coronary angiography and ad hoc angioplasty can be performed with similar efficacy, less local complication, earlier ambulation and better patient's satisfaction compared to the standard transfemoral approach.

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การศึกษาประสิทธิผล และความปลอดภัยของการฉีดสี และขยายหลอดเลือดหัวใจผ่านหลอดเลือดแดงบริเวณข้อมือเปรียบเทียบกับผ่านหลอดเลือดแดง บริเวณขาหนีบในโรงพยาบาลพระมงกุฎเกล้า

นครินทร์ ศันสนยุทธ, กิจจา จำปาศรี, ชุมพล เปี่ยมสมบูรณ์, โสภณ สงวนวงษ์, ชาญณรงค์ นาคสวัสดิ์, พรรณิภา เต็งตระกูลเจริญ, ประสาท เหล่าถาวร

วัตถุประสงค์: *เพื่อศึกษาความปลอดภัย และประสิทธิภาพของฉีดสี และขยายหลอดเลือดหัวใจผ่านหลอดเลือดแดงบริเวณข้อมือเปรียบเทียบกับผ่านหลอดเลือดแดง บริเวณขาหนีบในช่วงระยะแรกที่เริ่มทำการฉีดสี และขยายหลอดเลือดหัวใจผ่านหลอดเลือดแดงบริเวณข้อมือที่โรงพยาบาลพระมงกุฎเกล้า*

วัสดุและวิธีการ: *ทำการศึกษาแบบไปข้างหน้าในผู้ป่วยทุกรายที่รับการฉีดสีสวนหัวใจ และขยายหลอดเลือดหัวใจที่โรงพยาบาลพระมงกุฎเกล้า ตั้งแต่ ตุลาคม พ.ศ. 2547 ถึง มกราคม พ.ศ. 2548 ทำการบันทึกข้อมูลพื้นฐานและรายละเอียดการรักษาของผู้ป่วย วิเคราะห์เปรียบเทียบประสิทธิผล และความปลอดภัยของการทำหัตถการผ่านหลอดเลือดแดงบริเวณข้อมือเทียบกับผ่านหลอดเลือดแดงบริเวณขาหนีบ*

ผลการศึกษา: *มีจำนวนผู้ป่วยได้รับการทำการฉีดสีพร้อมทั้งขยายหลอดเลือดหัวใจทั้งหมด 75 ราย ในช่วง 4 เดือนที่ทำการศึกษา ผ่านหลอดเลือดแดงบริเวณข้อมือ 23 ราย (ร้อยละ 30.7) และผ่านหลอดเลือดแดงบริเวณขาหนีบ 52 ราย (ร้อยละ 69.3) ทั้งสองกลุ่มพบความแตกต่างอย่างไม่มีนัยสำคัญทางสถิติในเรื่องของเวลาที่ใช้ในการทำหัตถการ เวลาที่สัมผัสรังสี และปริมาณสารทึบรังสีที่ใช้ อัตราความสำเร็จของการทำผ่านหลอดเลือดแดง บริเวณข้อมือสูงมากกว่าร้อยละ 90 และไม่ต่างกับการทำผ่านหลอดเลือดแดงบริเวณขาหนีบ อย่างไรก็ตามพบว่ากลุ่มทำผ่านหลอดเลือดแดงบริเวณข้อมือมีผลแทรกซ้อนเฉพาะที่น้อยกว่า (ร้อยละ 4.35 เทียบกับร้อยละ 22.08, p = 0.035) และผู้ป่วยสามารถลุกนั่ง และเริ่มเดินได้เร็วกว่า อีกทั้งความพึงพอใจของผู้ป่วยยังมากกว่าการทำผ่านหลอดเลือดแดงบริเวณขา*

สรุป: *แม้ในโรงพยาบาลที่เพิ่งเริ่มทำการฉีดสี และขยายหลอดเลือดหัวใจผ่านหลอดเลือดแดงบริเวณข้อมือ พบว่าการฉีดสี และขยายหลอดเลือดหัวใจผ่านหลอดเลือดแดงบริเวณข้อมือ มีภาวะแทรกซ้อนน้อยกว่า ผู้ป่วยเริ่มลุกนั่งและเดินได้เร็วกว่า และมีประสิทธิภาพ และอัตราความสำเร็จสูงไม่ต่างกับการทำผ่านหลอดเลือดแดงบริเวณขาหนีบ*